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(54) **IMPLANT FOR HEART VALVE**

(71) Applicant: **CARDIOVALVE LTD.**, Or Yehuda (IL)

(72) Inventors: **Yossi Gross**, Moshav Mazor (IL); **Gil Hacohen**, Ramat Gan (IL)

(73) Assignee: **CARDIOVALVE LTD.**, Or Yehuda (IL)

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See application file for complete search history.

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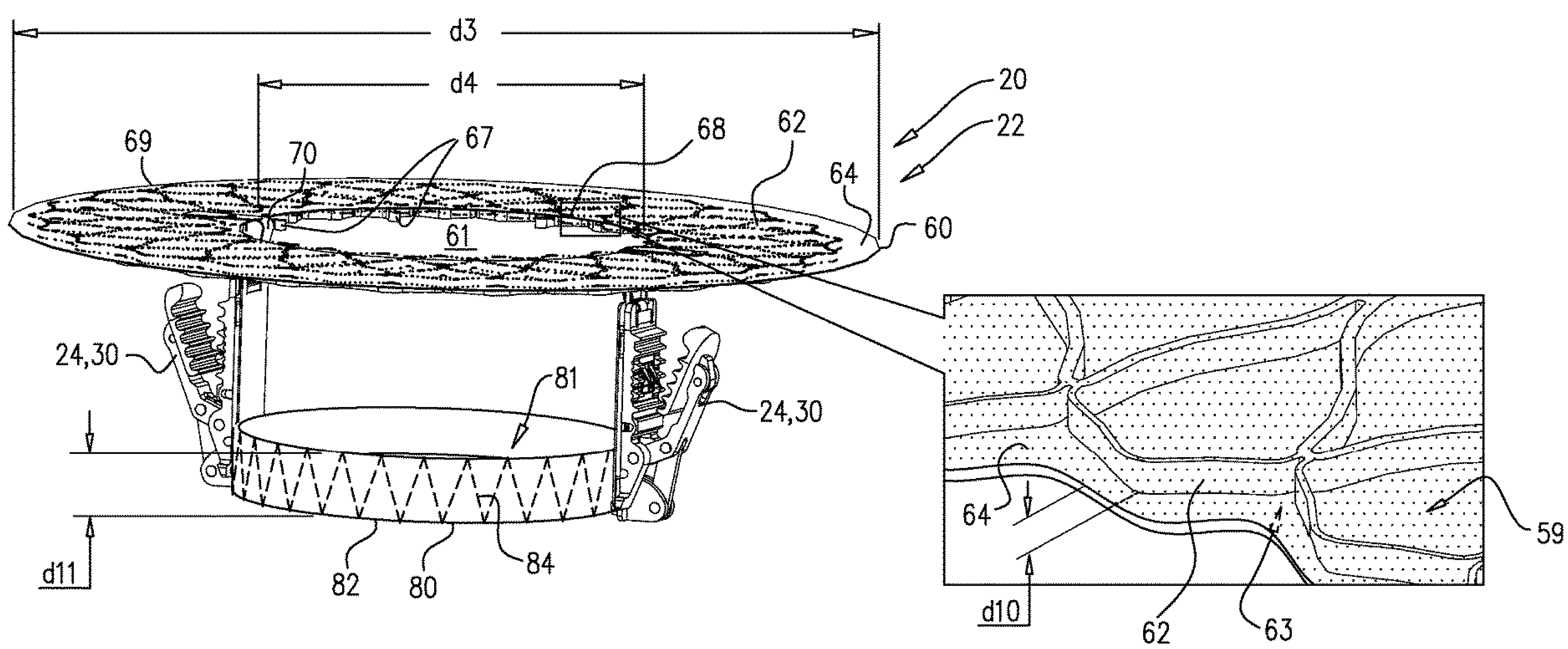
*Primary Examiner* — Suzette J Gherbi
(74) *Attorney, Agent, or Firm* — Sughrue Mion, PLLC

(57) **ABSTRACT**

A heart valve repair system includes a delivery sheath and an implant that includes a frame including a braided structure of intertwining strands and having a surface configured to contact an upstream surface of a native heart valve. First and second gripping members are coupled to the frame, each including atrial and ventricular arms. The implant is disposed in the sheath in a delivery state in which the frame defines a wall fully surrounding a central longitudinal axis of the implant. The distal end of the wall defines a distal opening of the frame. The distal end of the wall is disposed proximally to the second end of the ventricular arm of each of the gripping members. The second end of each ventricular arm moves toward the axis of the implant more than the first end moves toward the axis. Other embodiments are also described.

**28 Claims, 13 Drawing Sheets**



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Ex Parte Quayle dated May 2, 2022, which issued during the prosecution of U.S. Appl. No. 16/879,952.
IPR2021-00383 Final Written Decision dated Jul. 18, 2022.
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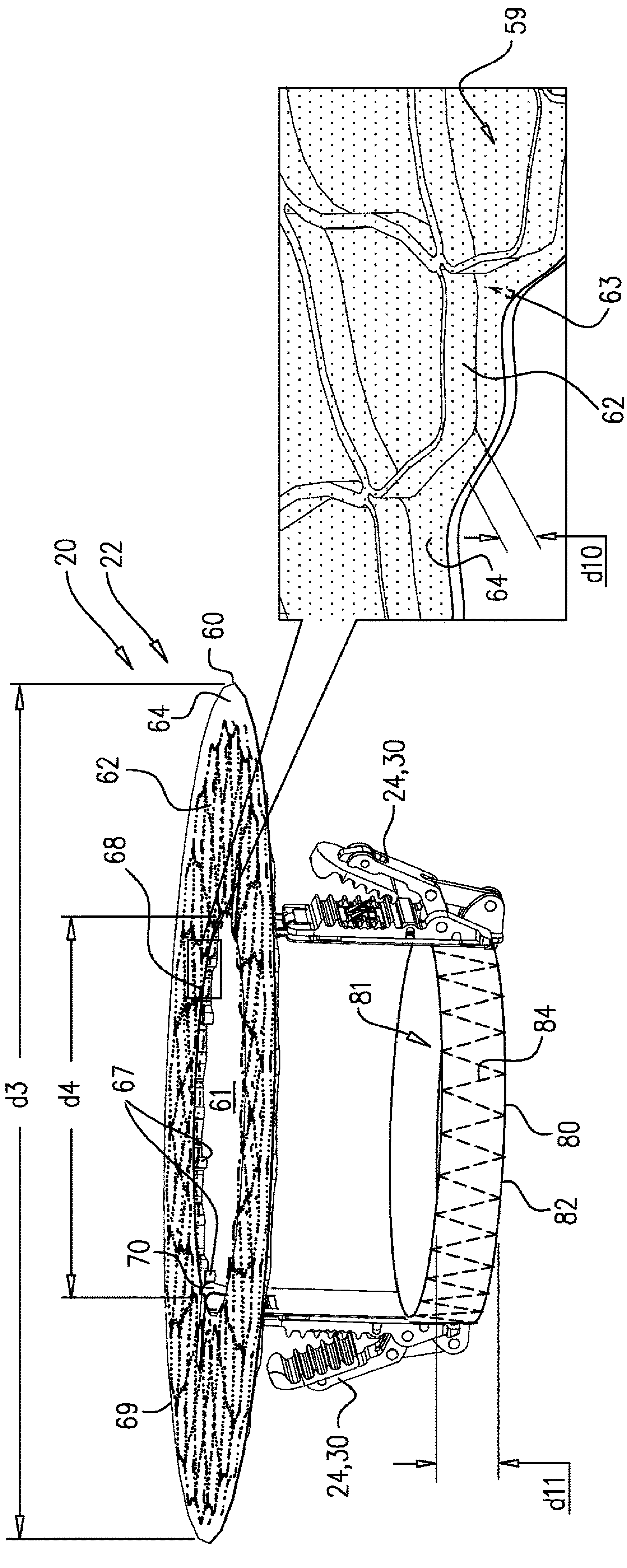
FIG. 1A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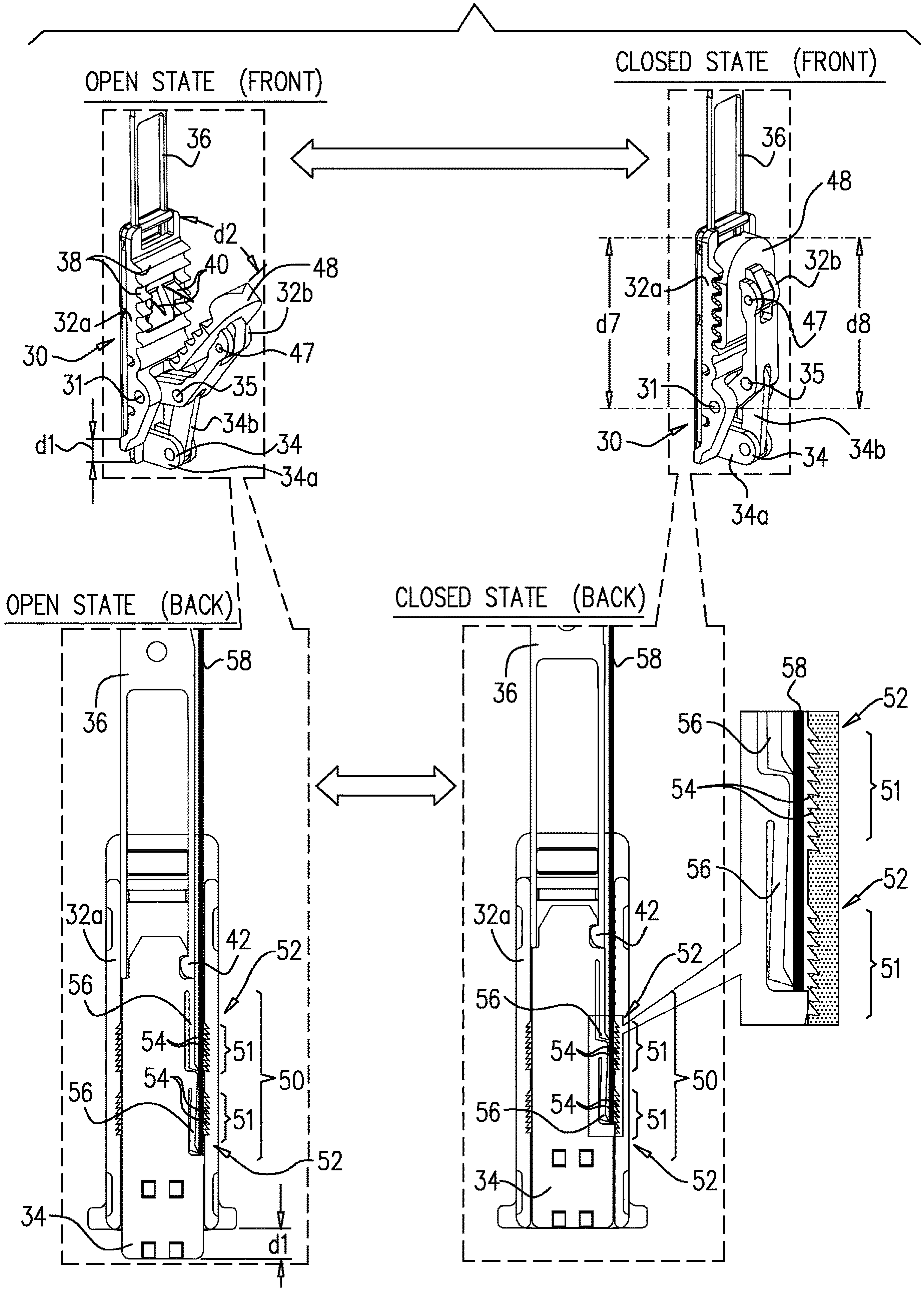
d11

FIG. 1B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CLOSED STATE (FRONT)
OPEN STATE (BACK)
CLOSED STATE (BACK)
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d2
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32b
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d8
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FIG. 1D

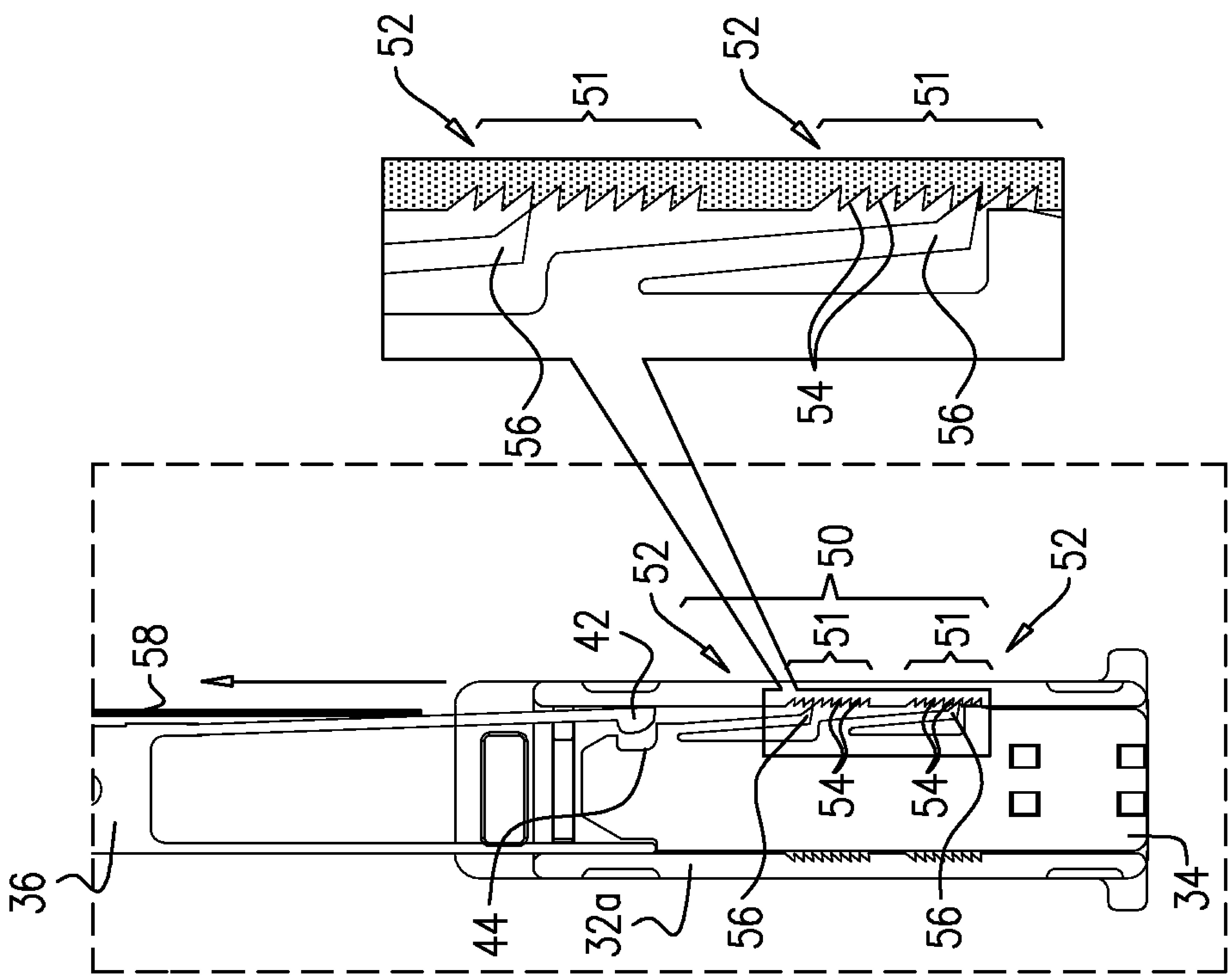
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FIG. 1C

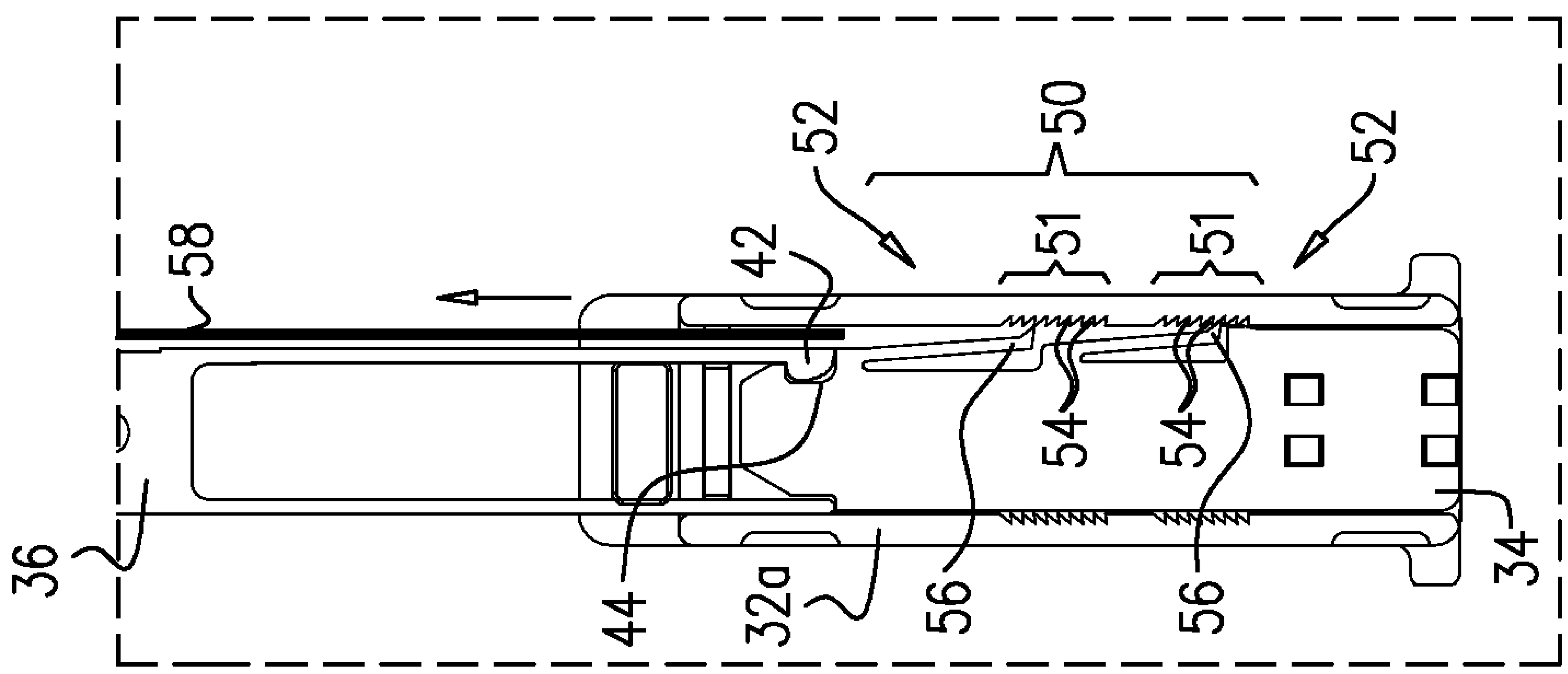
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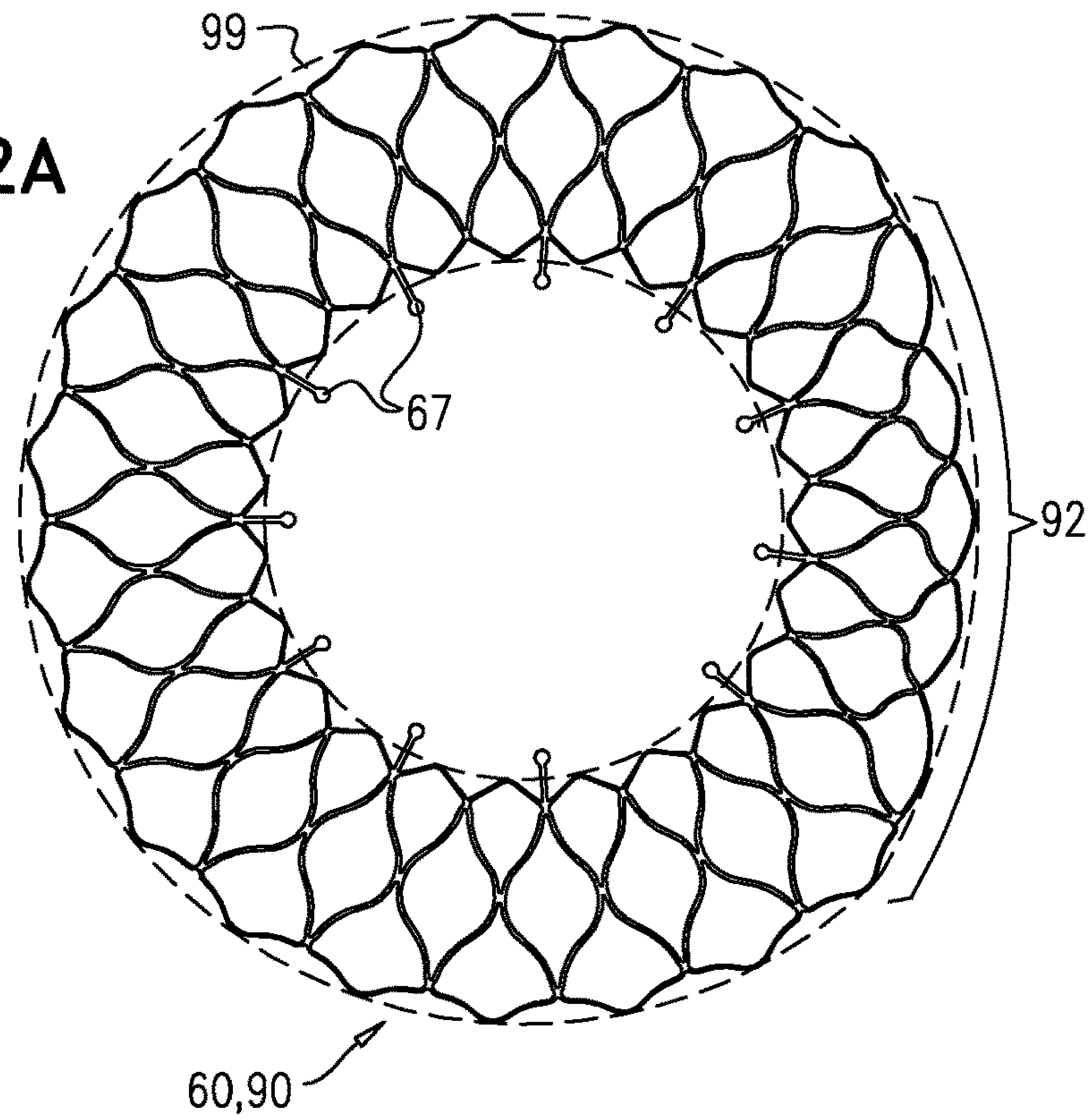
FIG. 2A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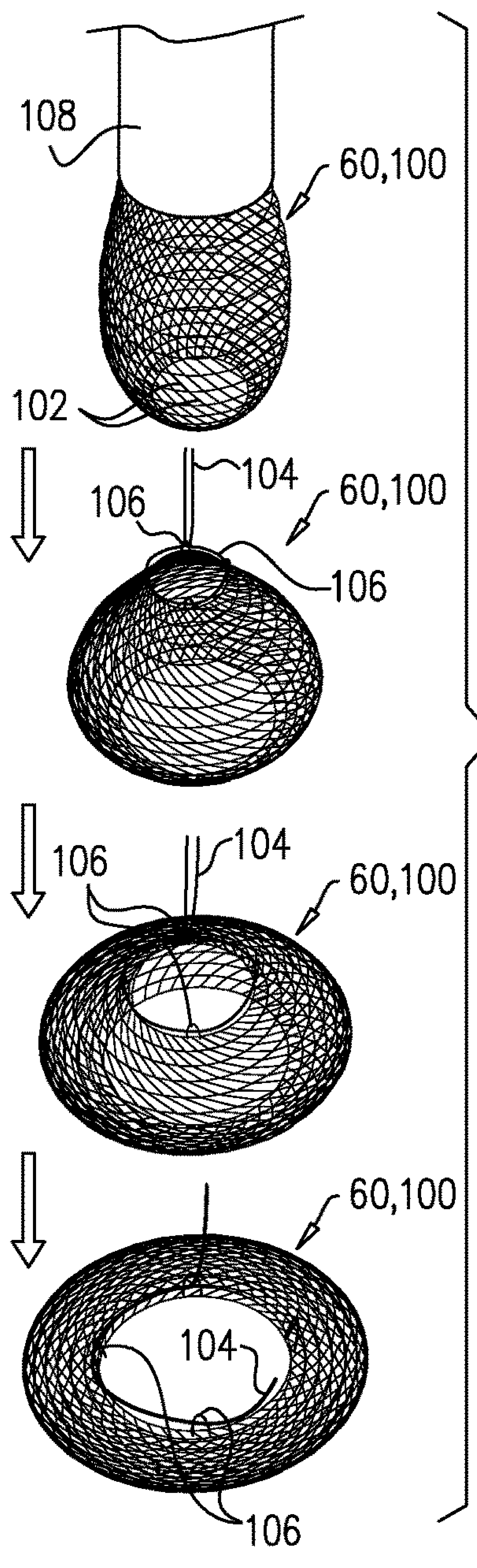
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FIG. 2B

FIG. 2C

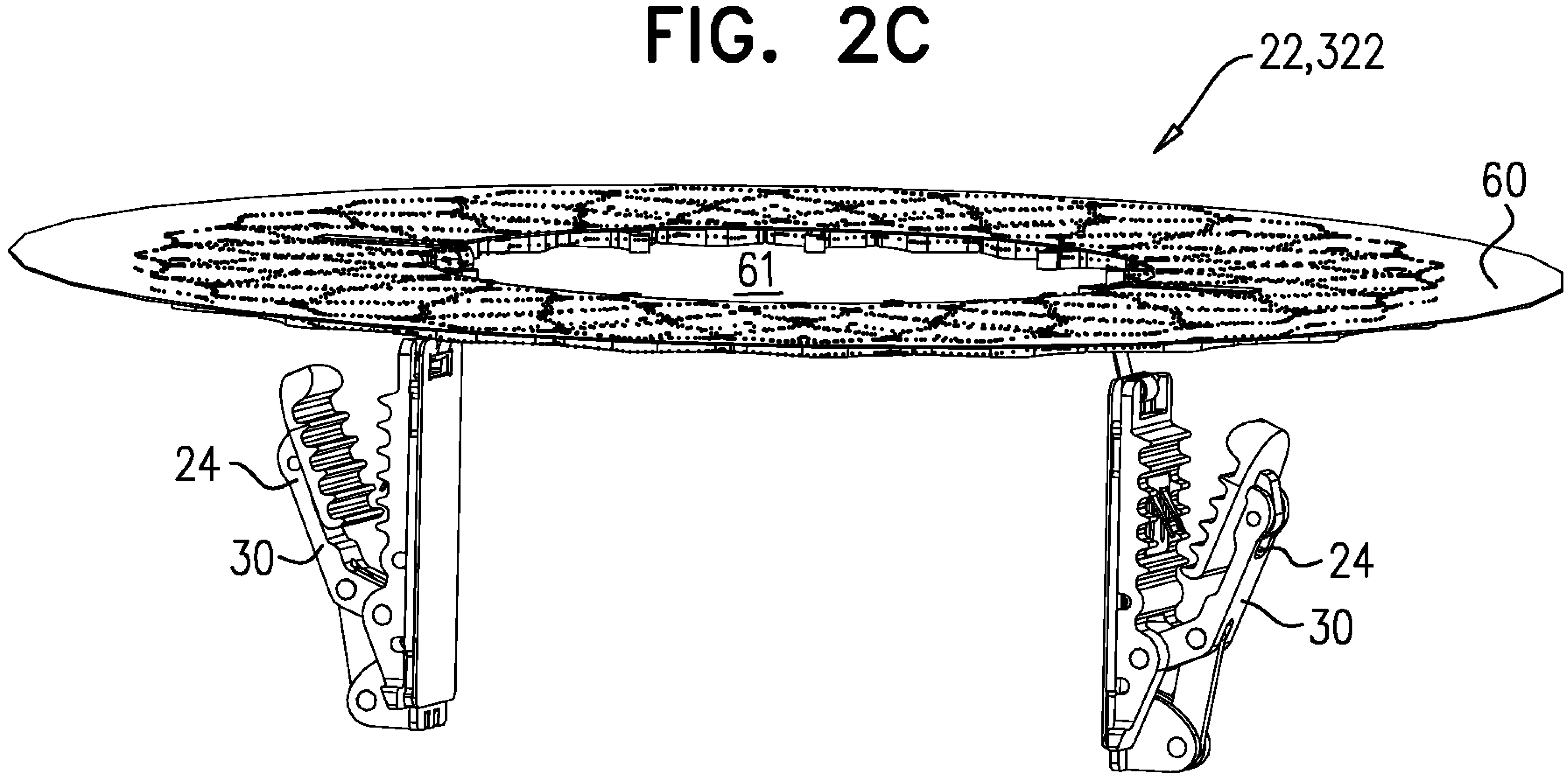


FIG. 2D

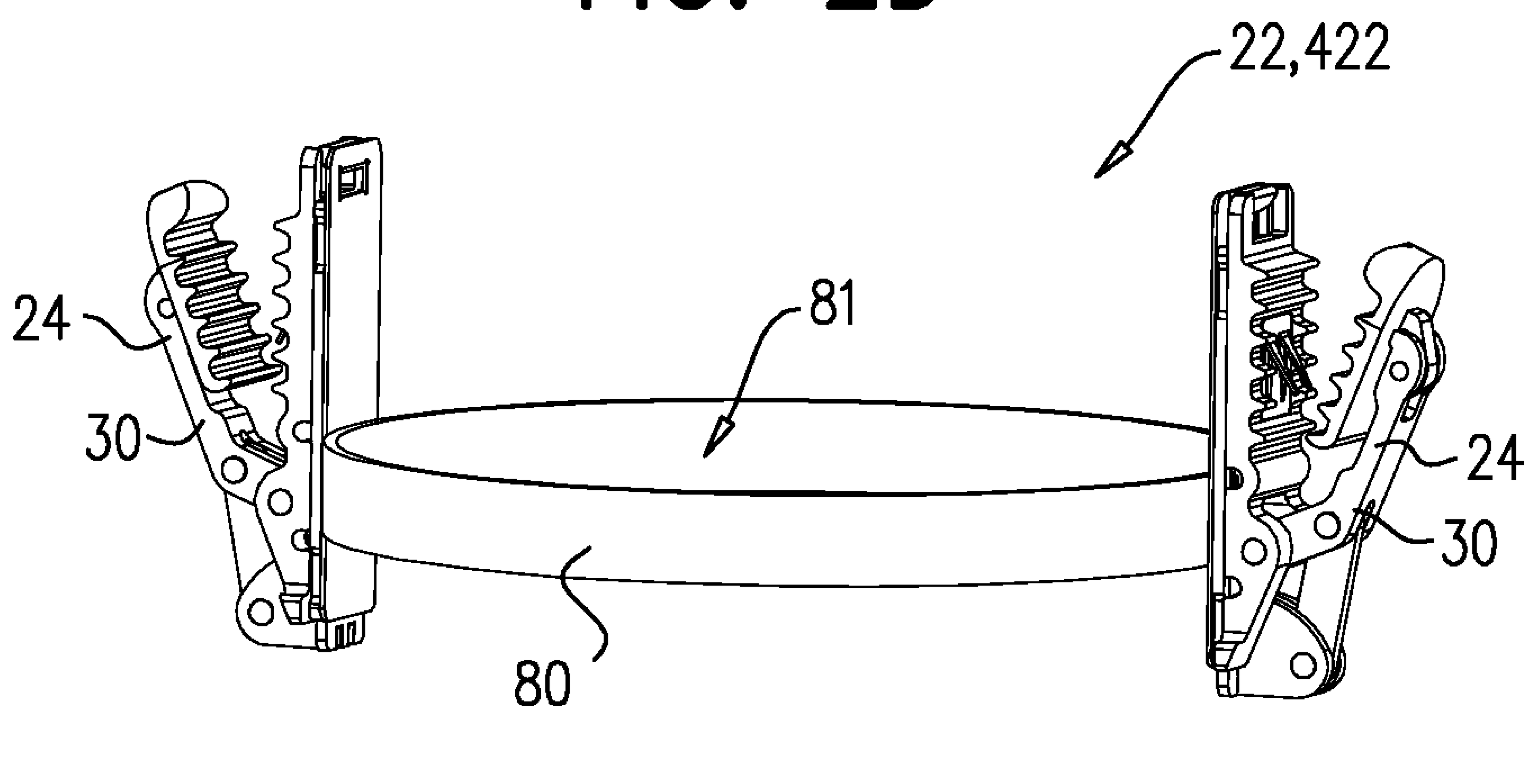

FIG. 3A

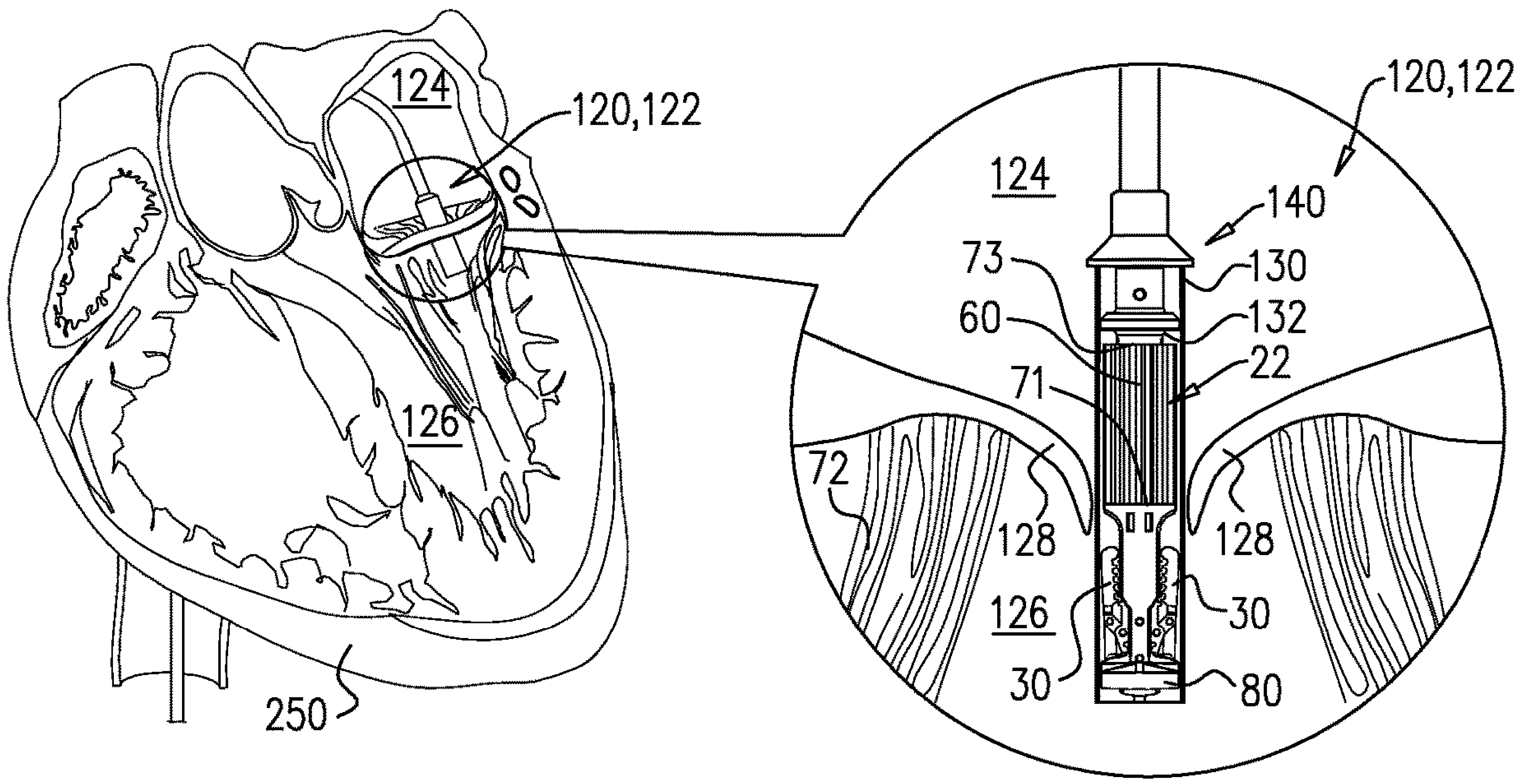
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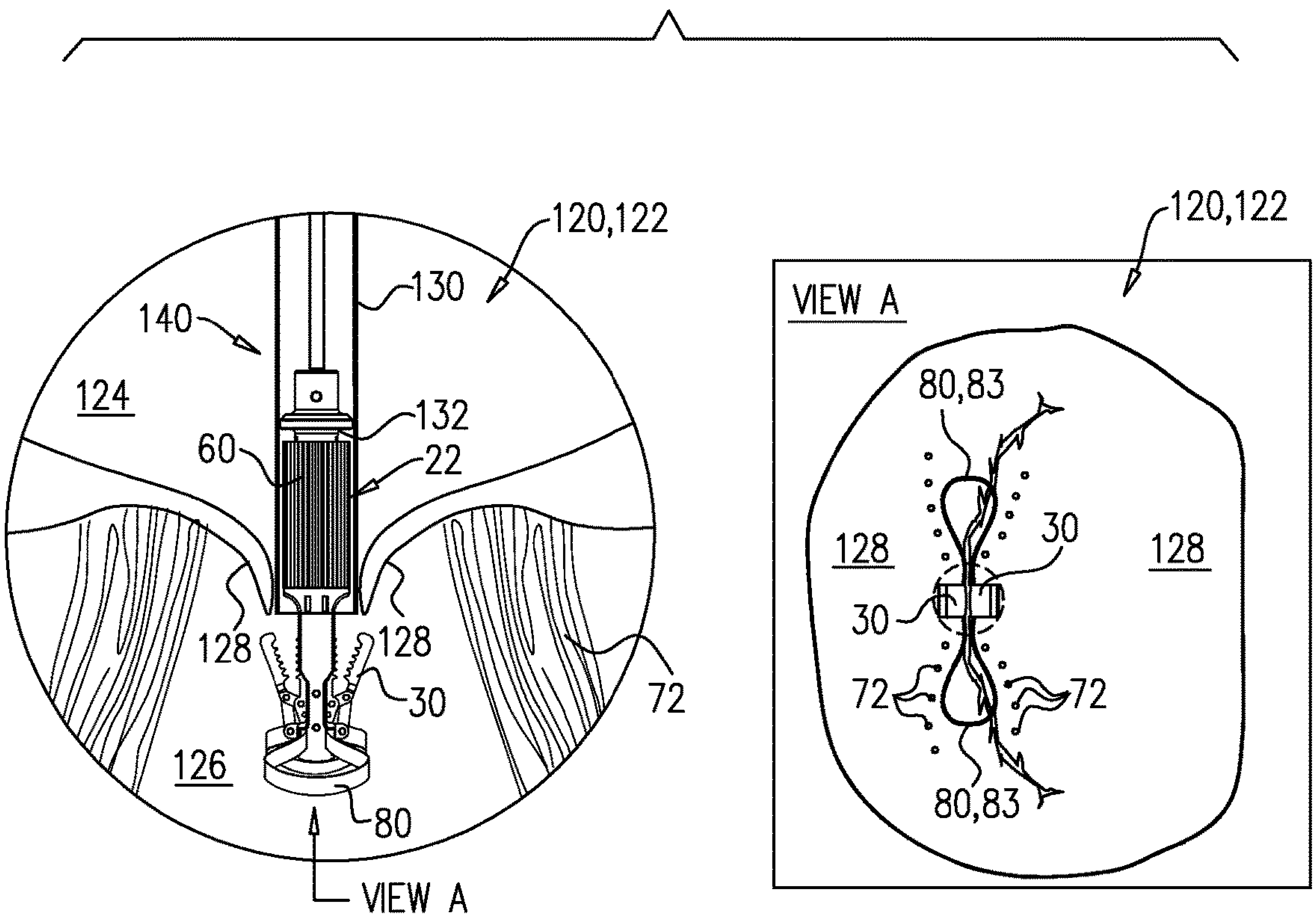
FIG. 3B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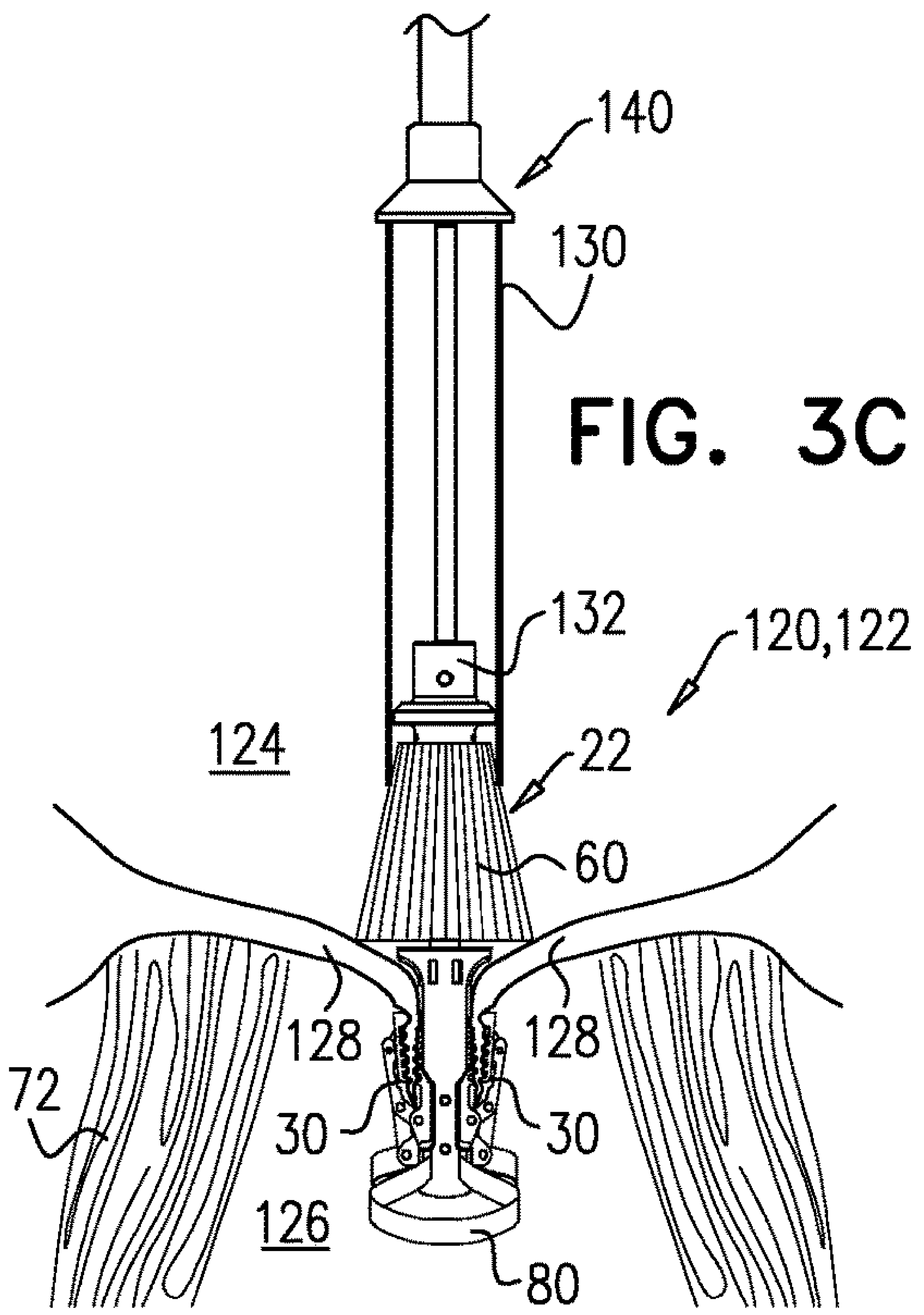



FIG. 3C

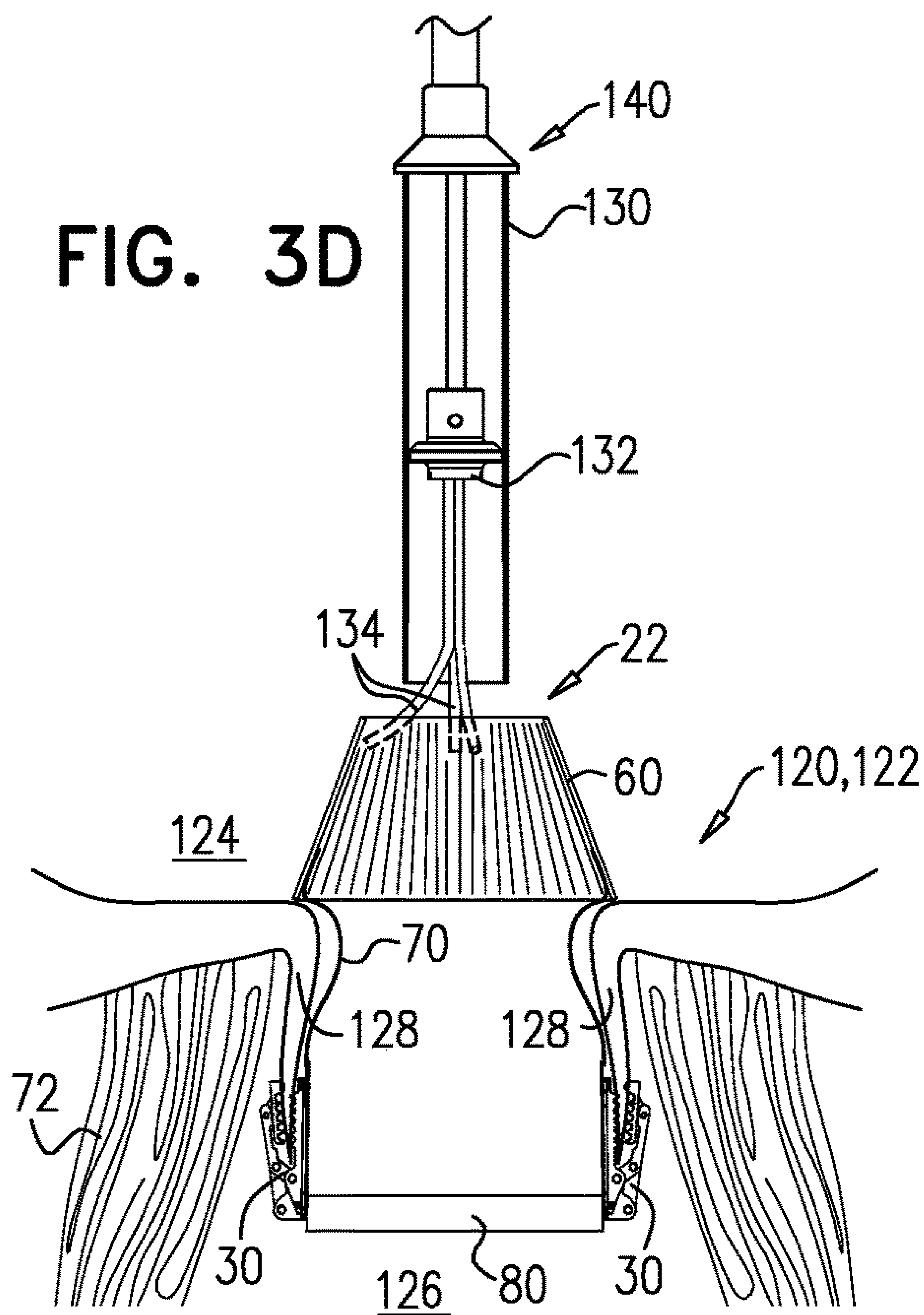



FIG. 3D

FIG. 3E

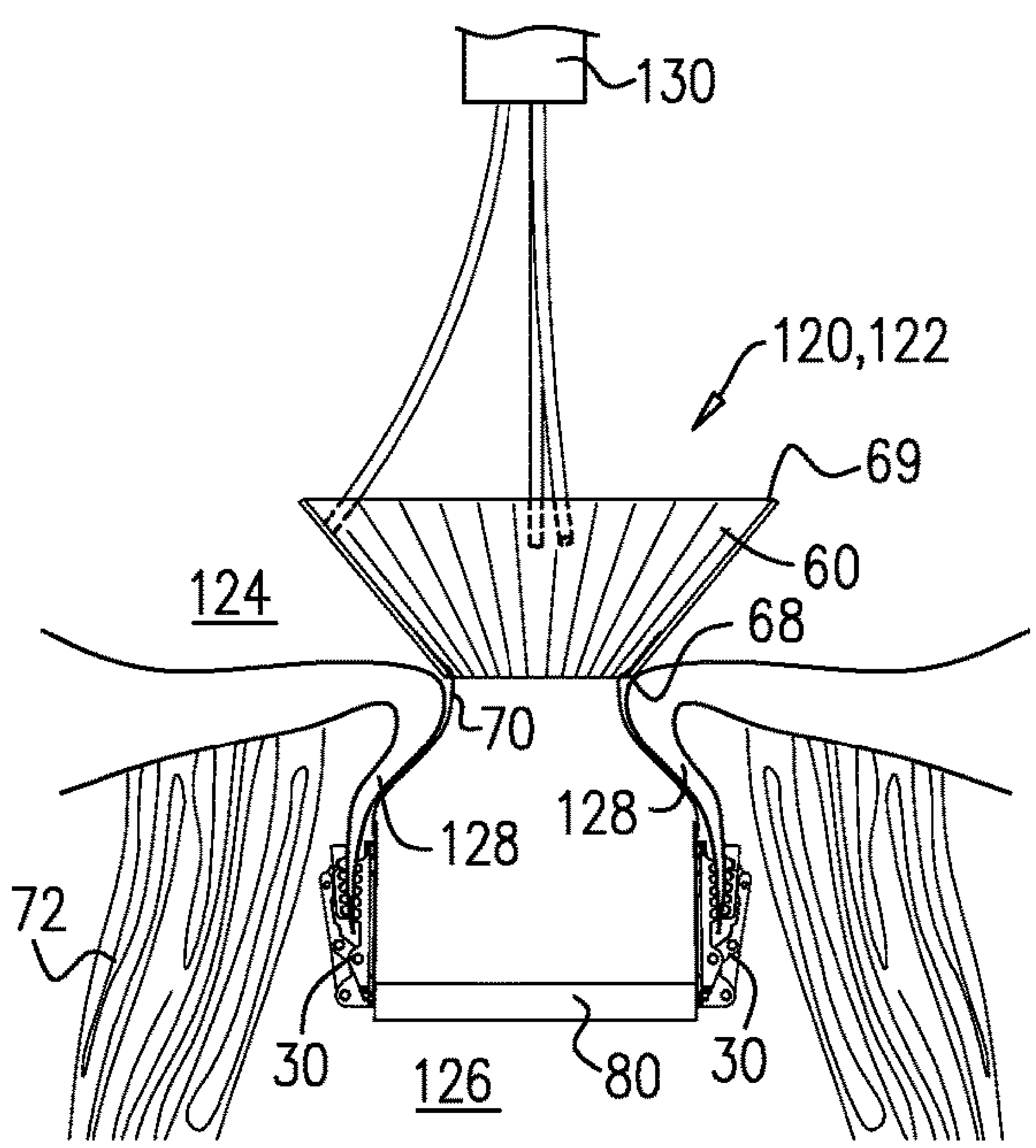
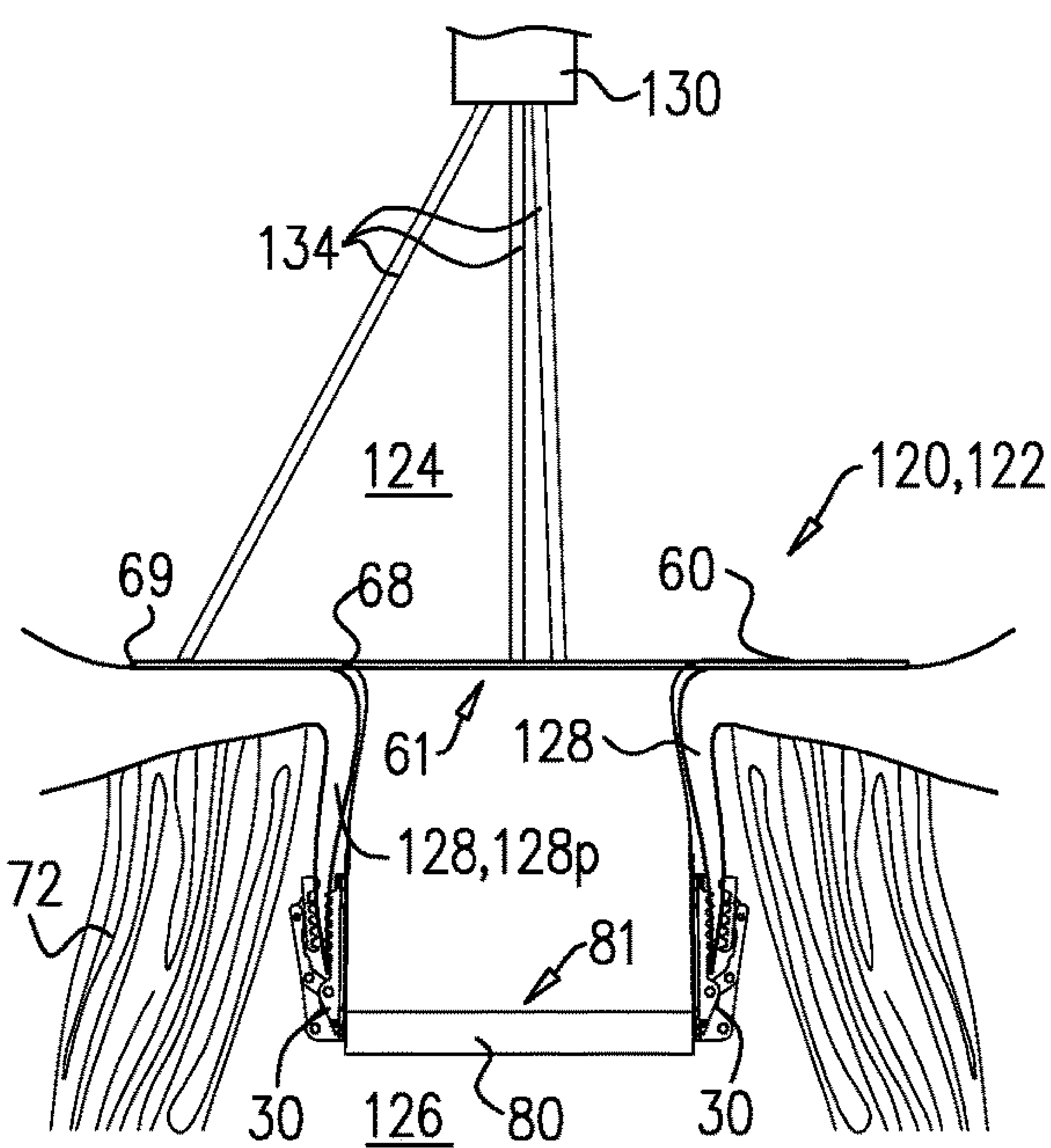



FIG. 3F



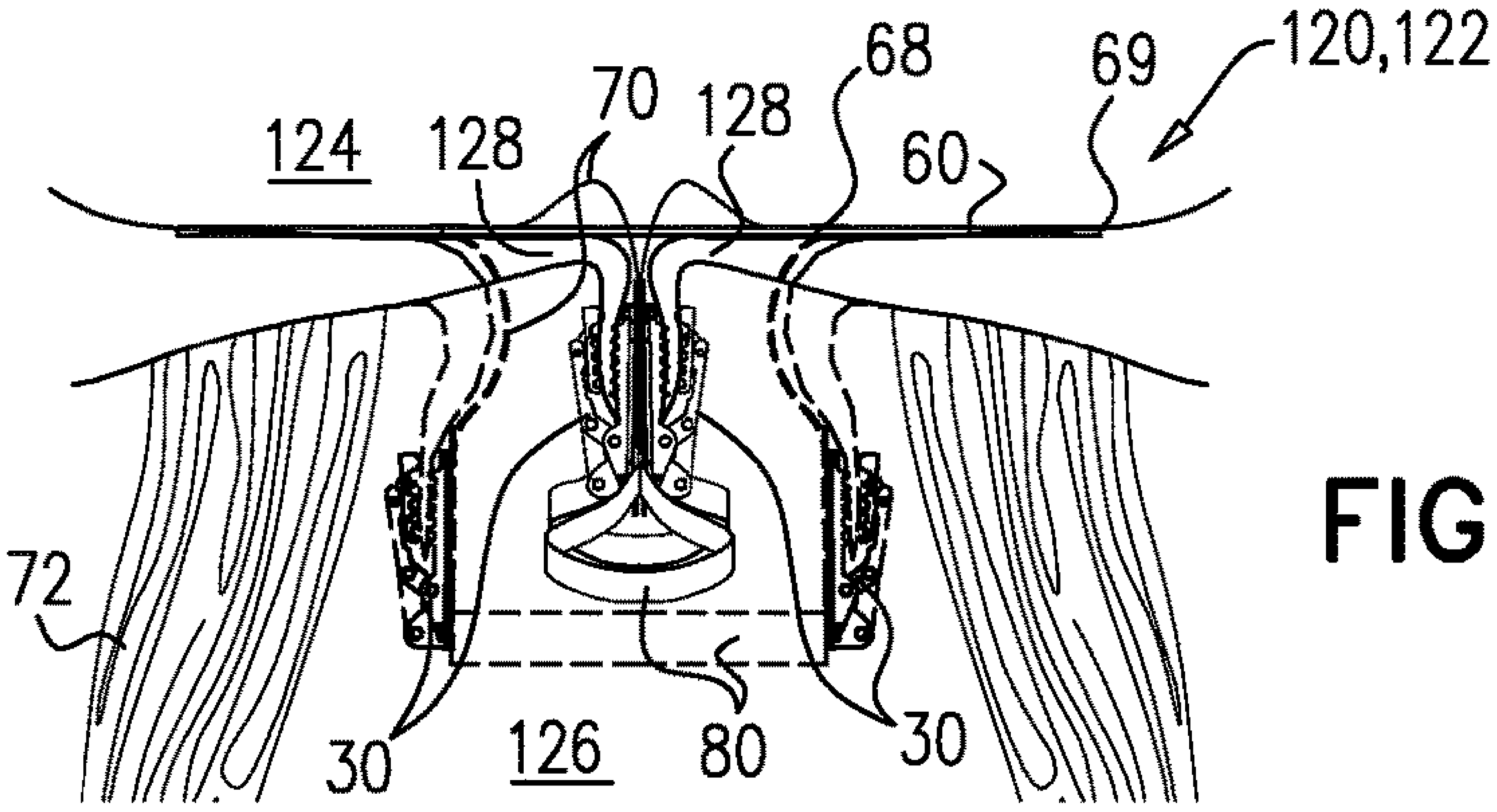



FIG. 3G

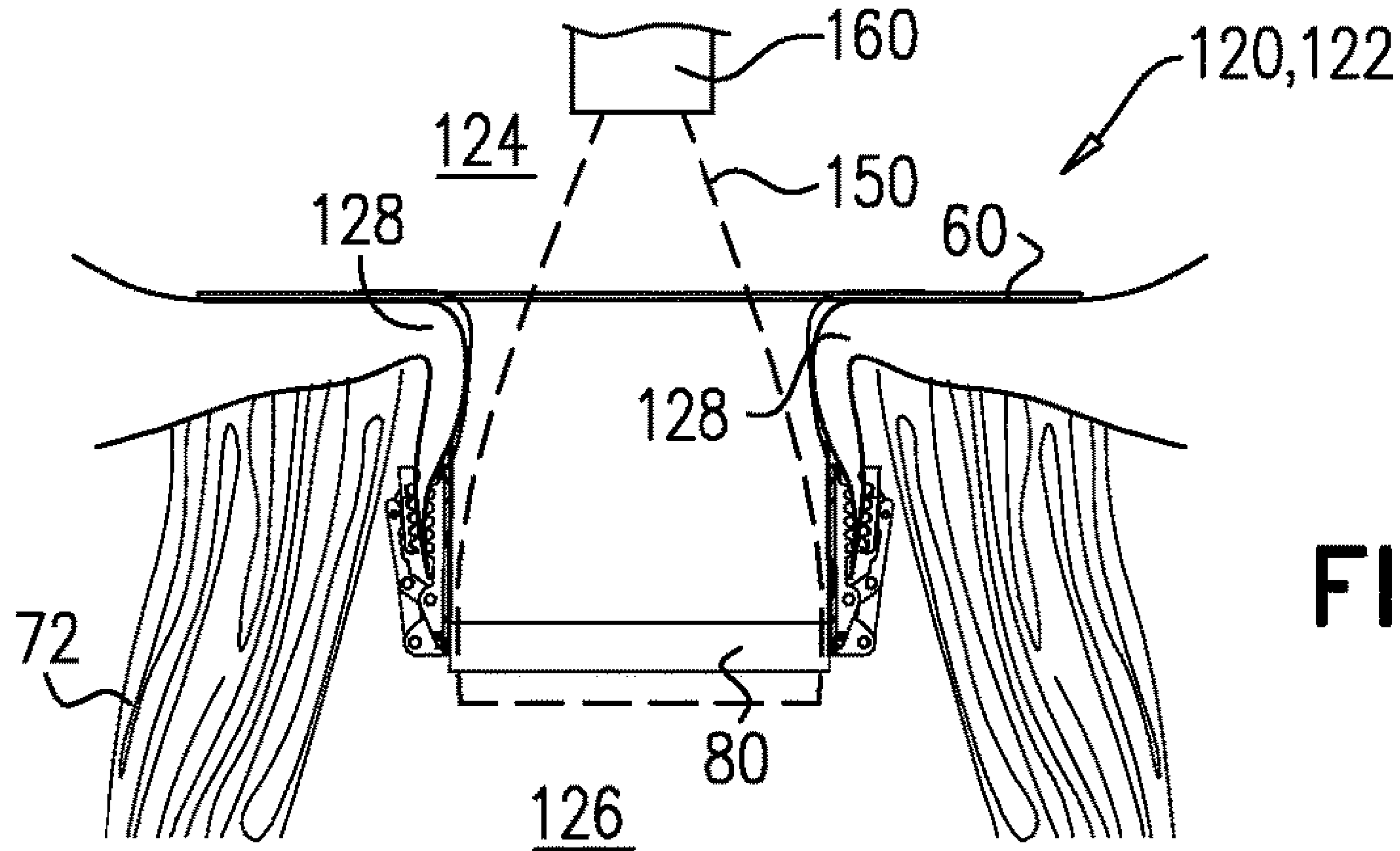



FIG. 3H

FIG. 3I

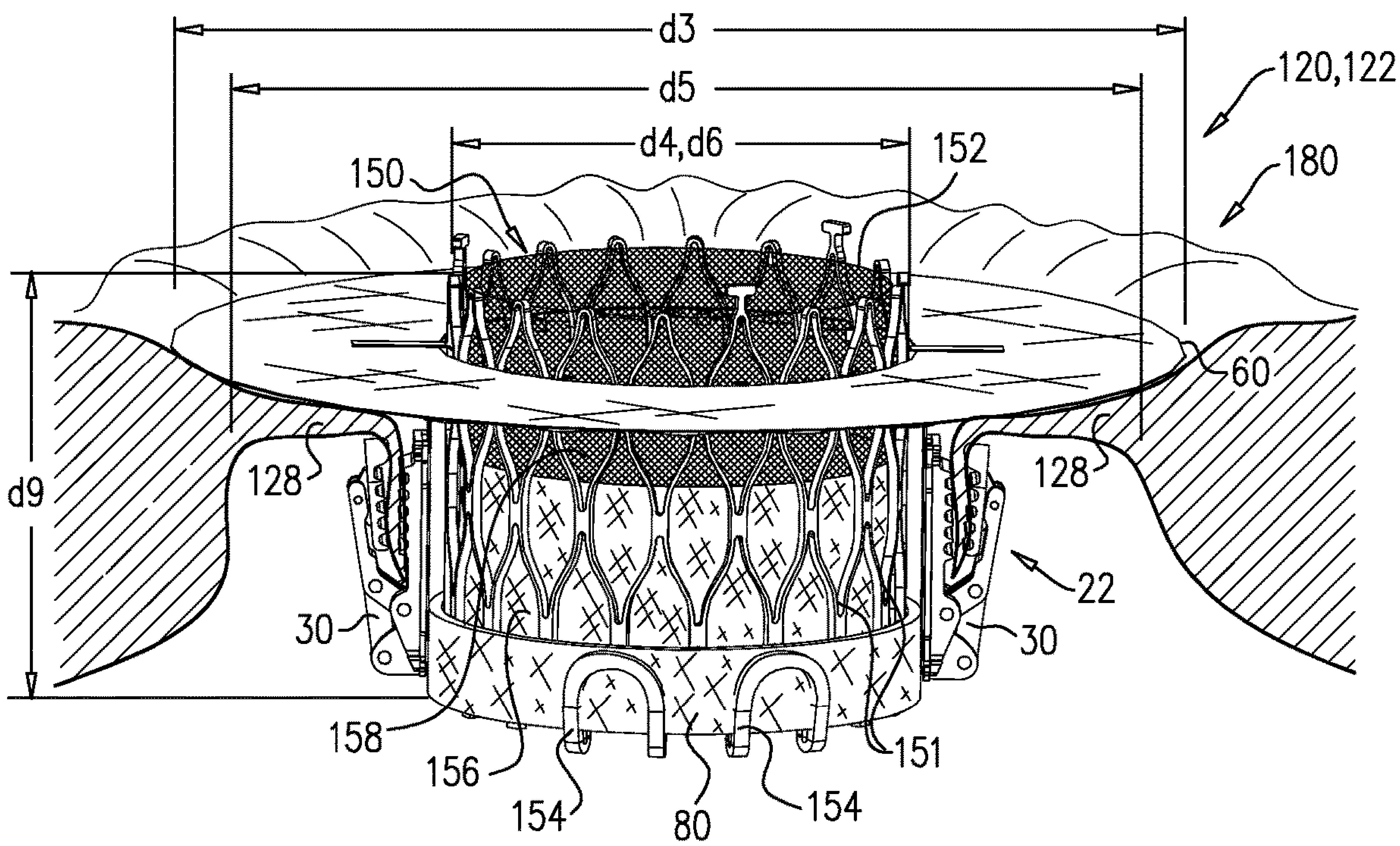


FIG. 4A

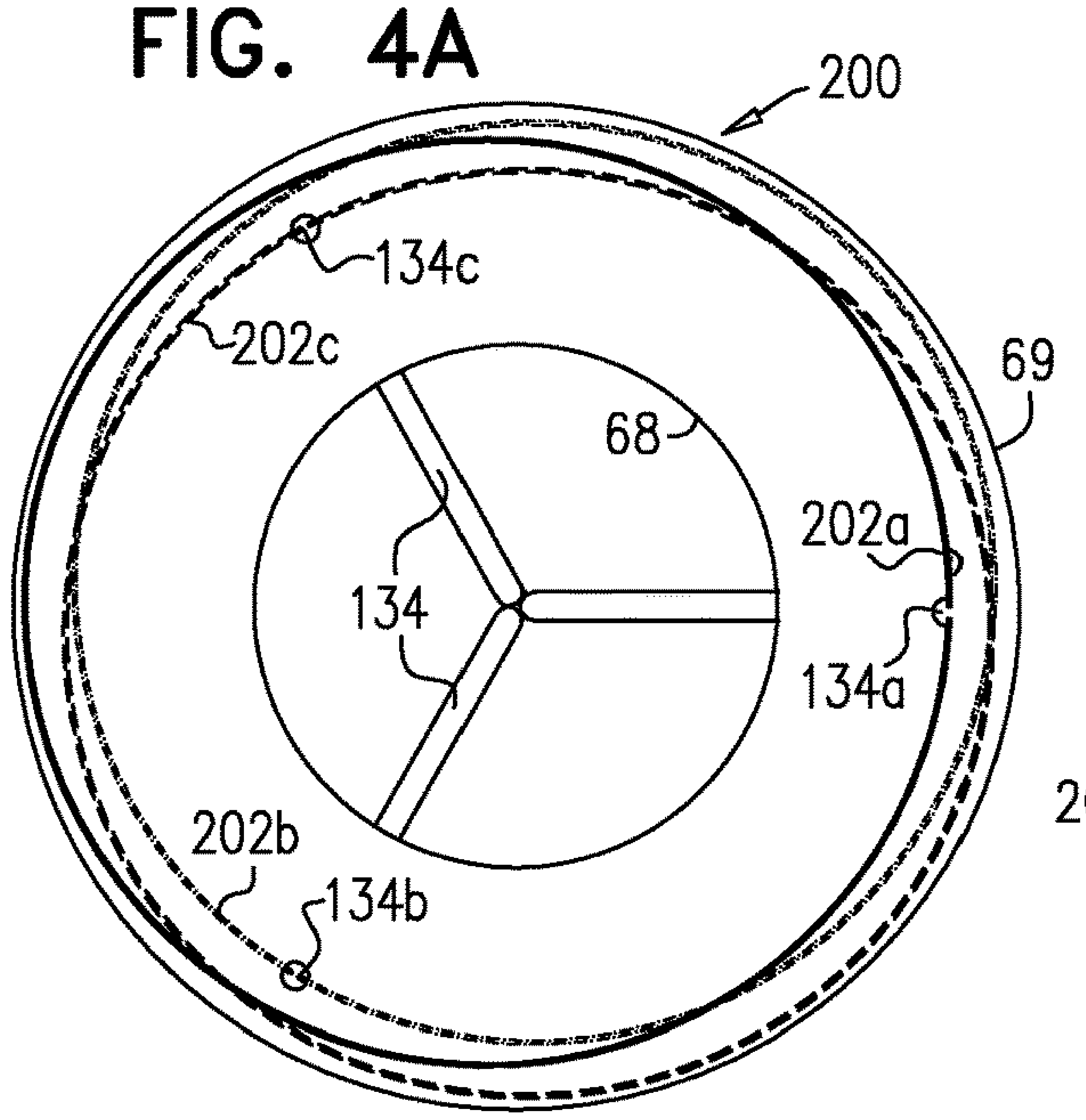



FIG. 4B

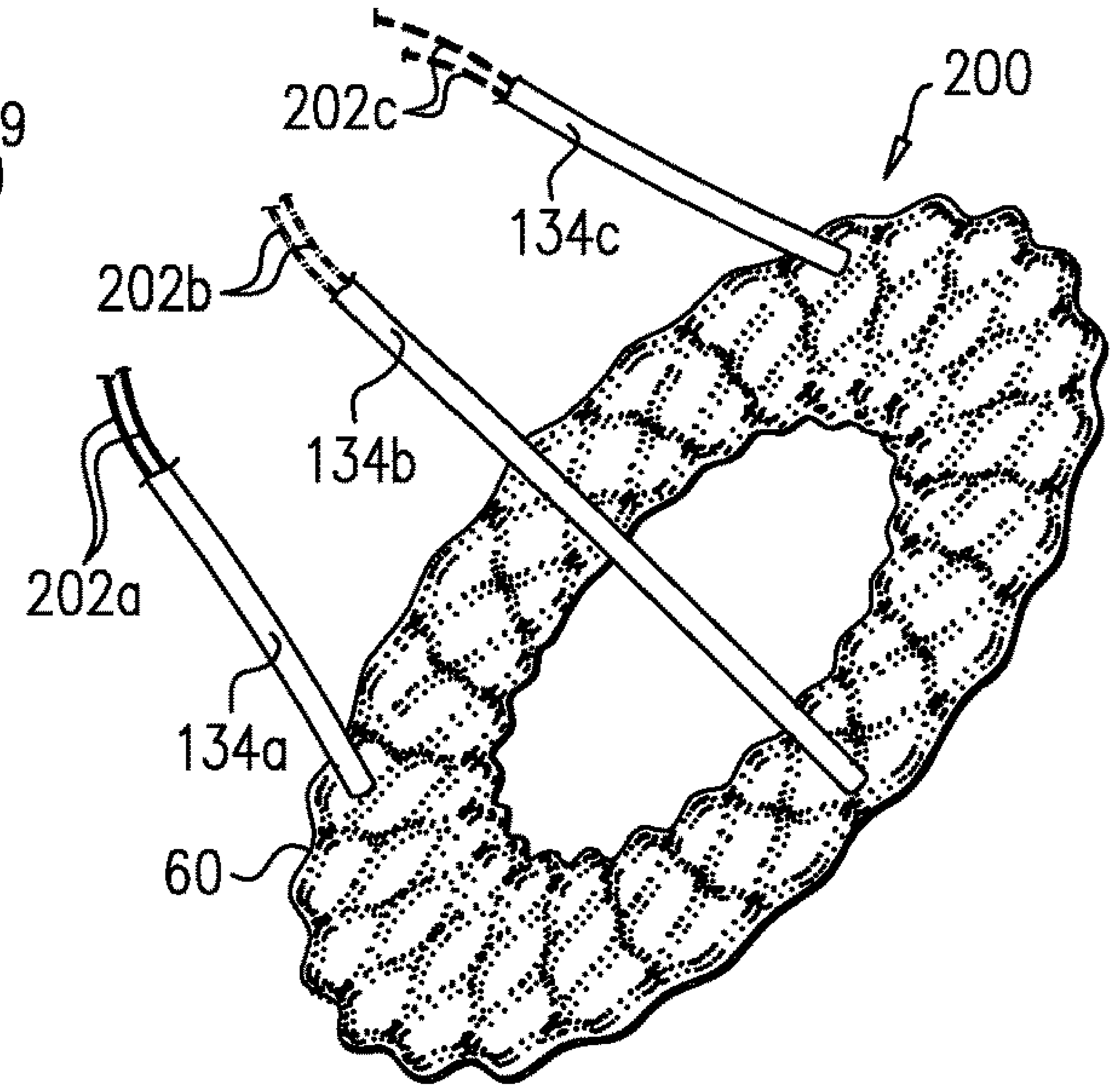



FIG. 4C

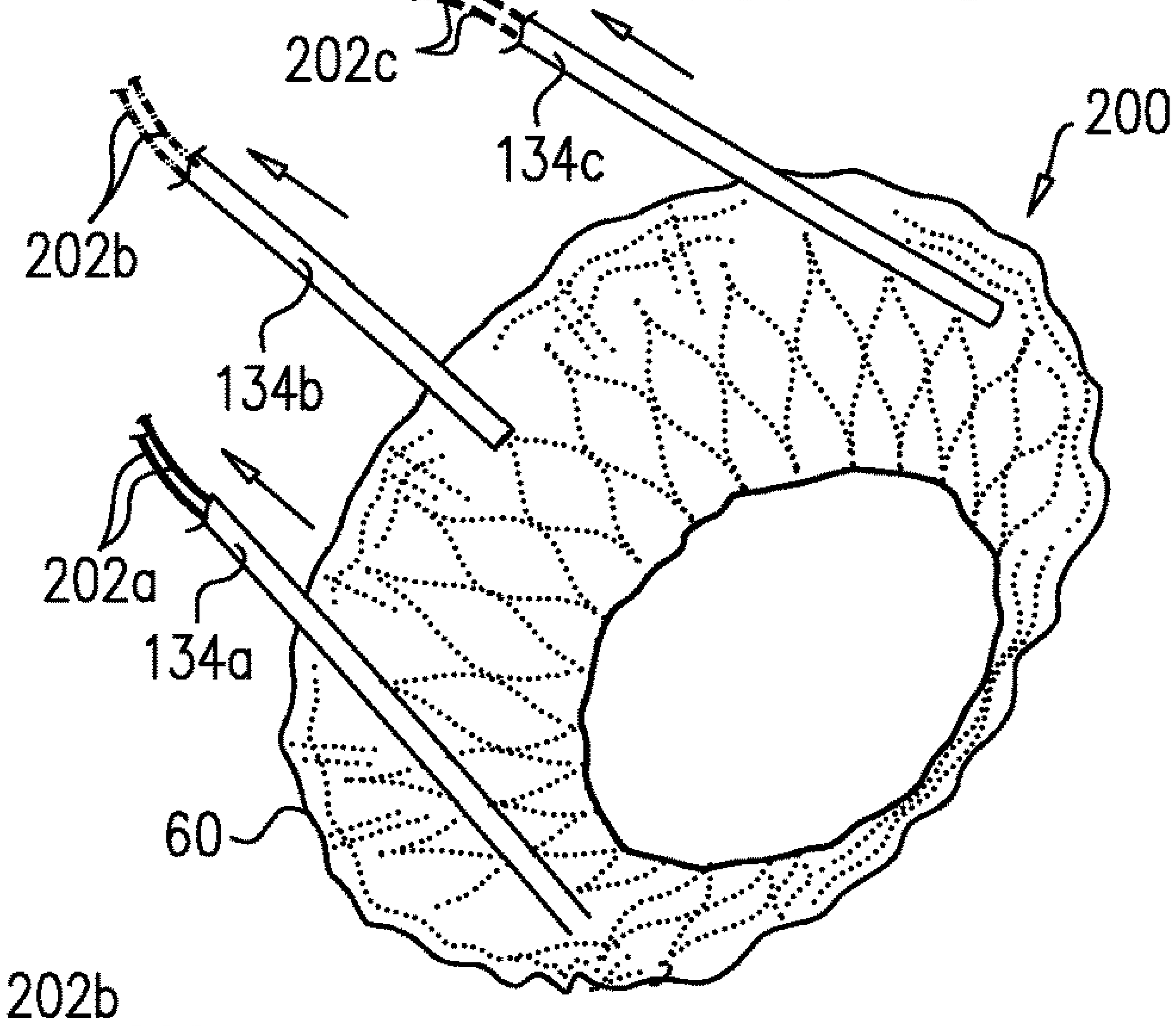



FIG. 4D

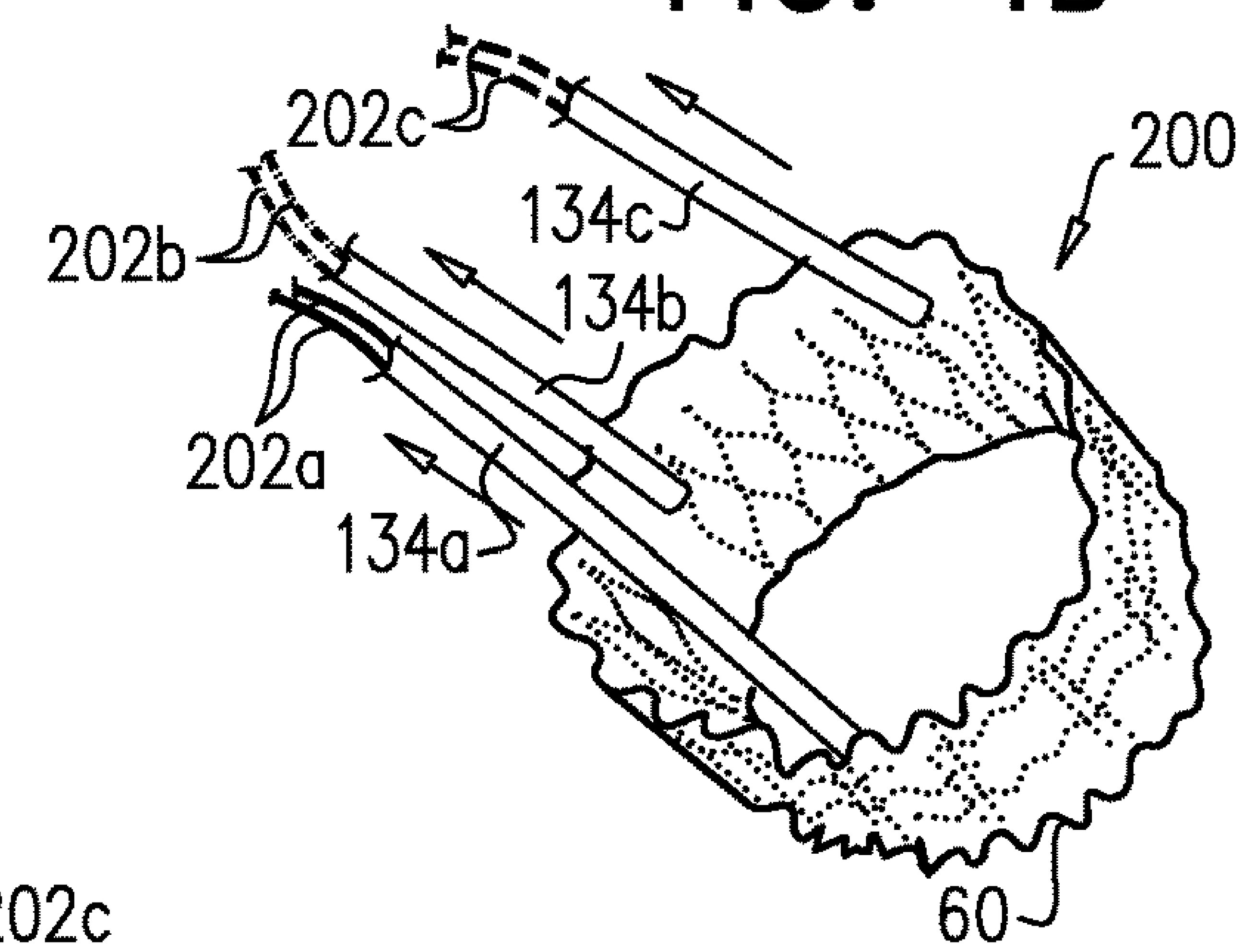



FIG. 4E

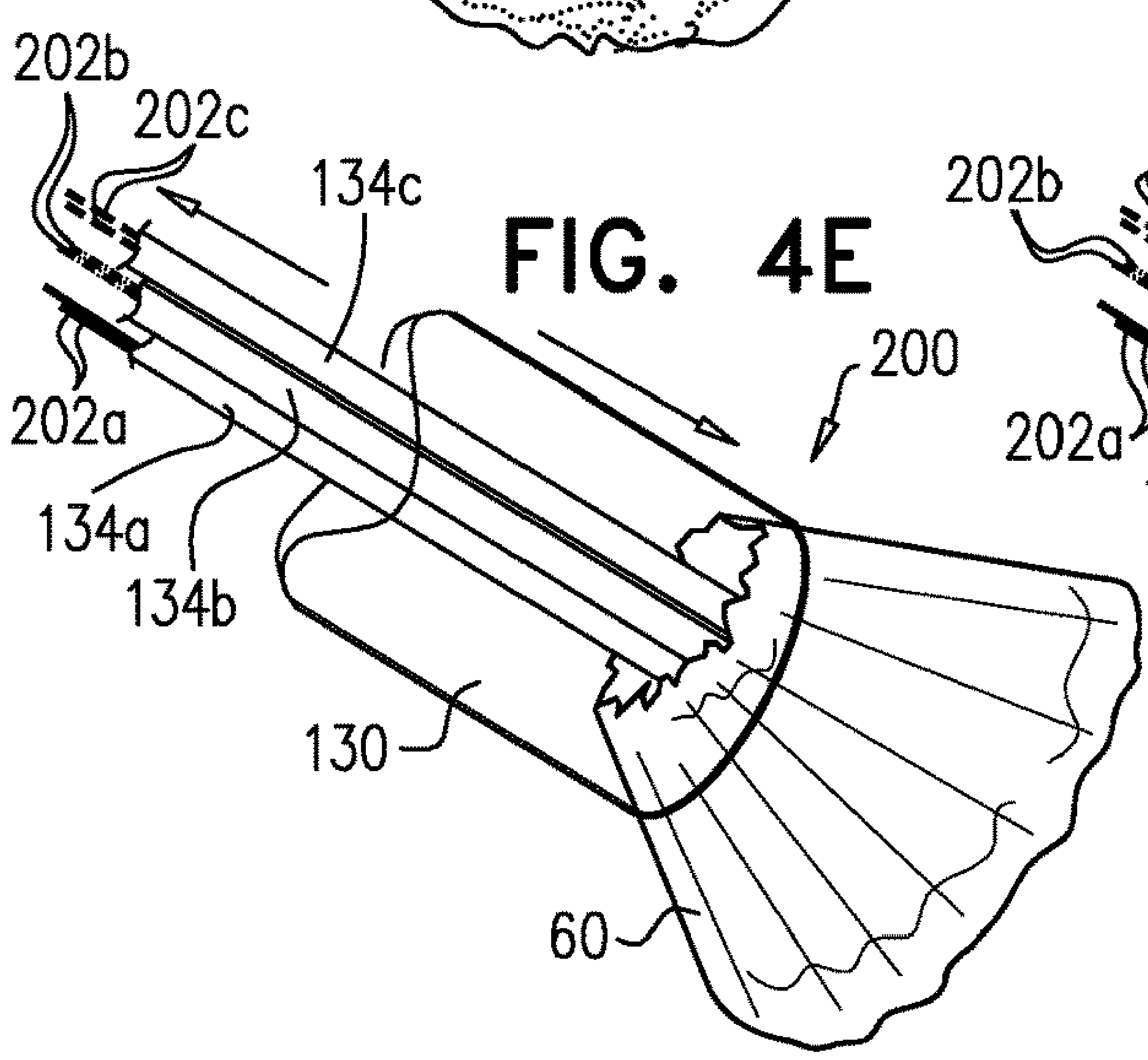



FIG. 4F

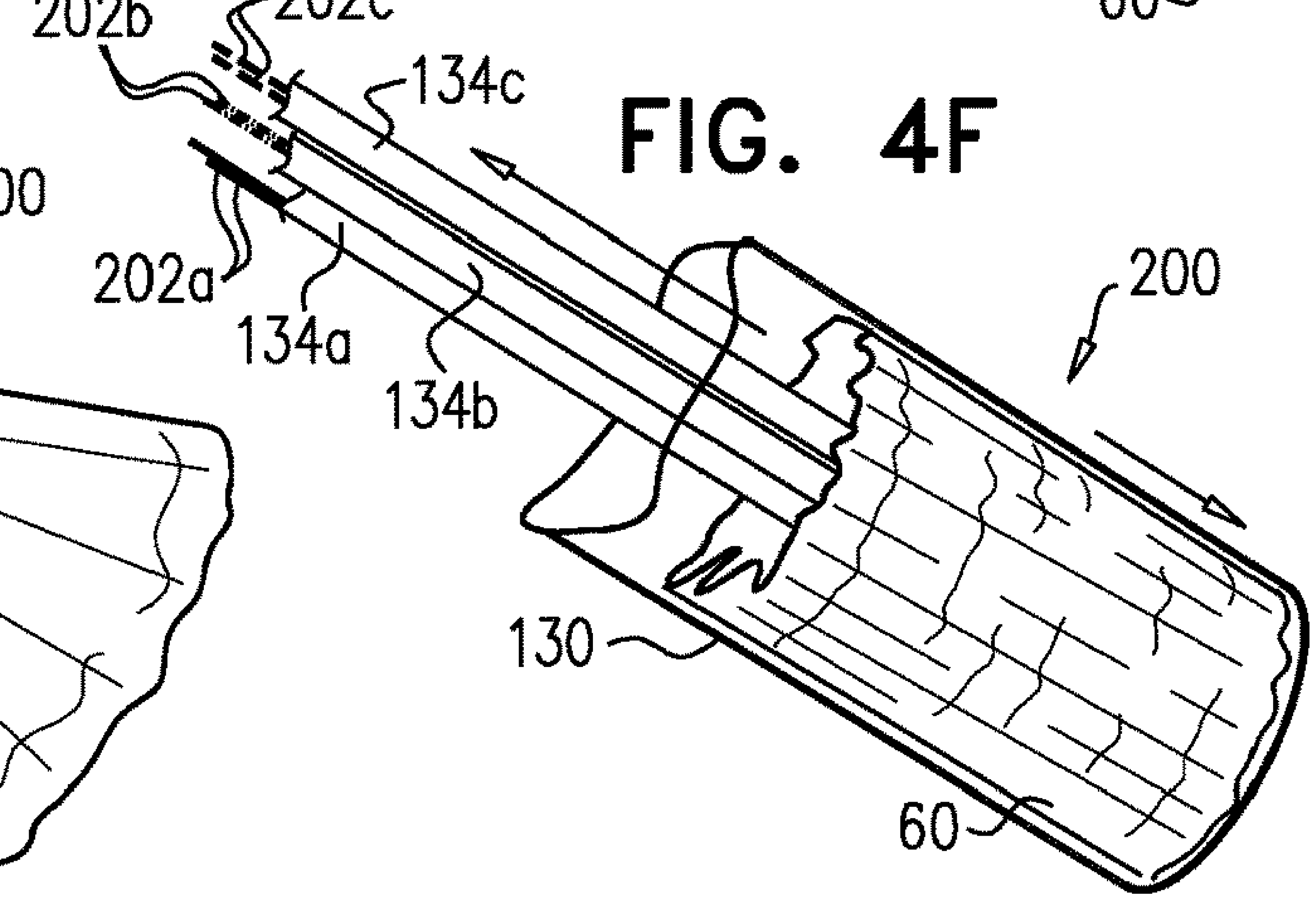


FIG. 5

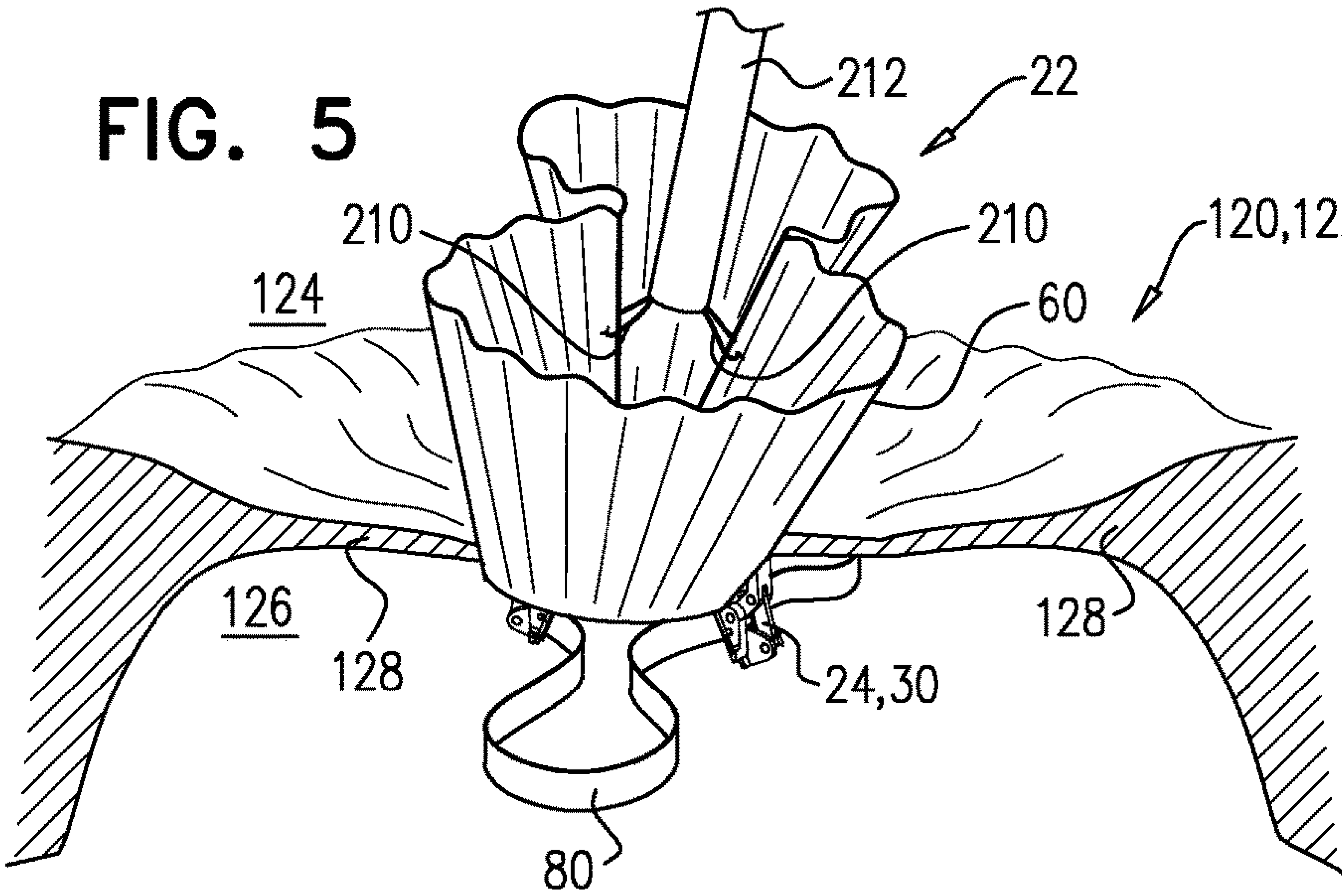



FIG. 6A

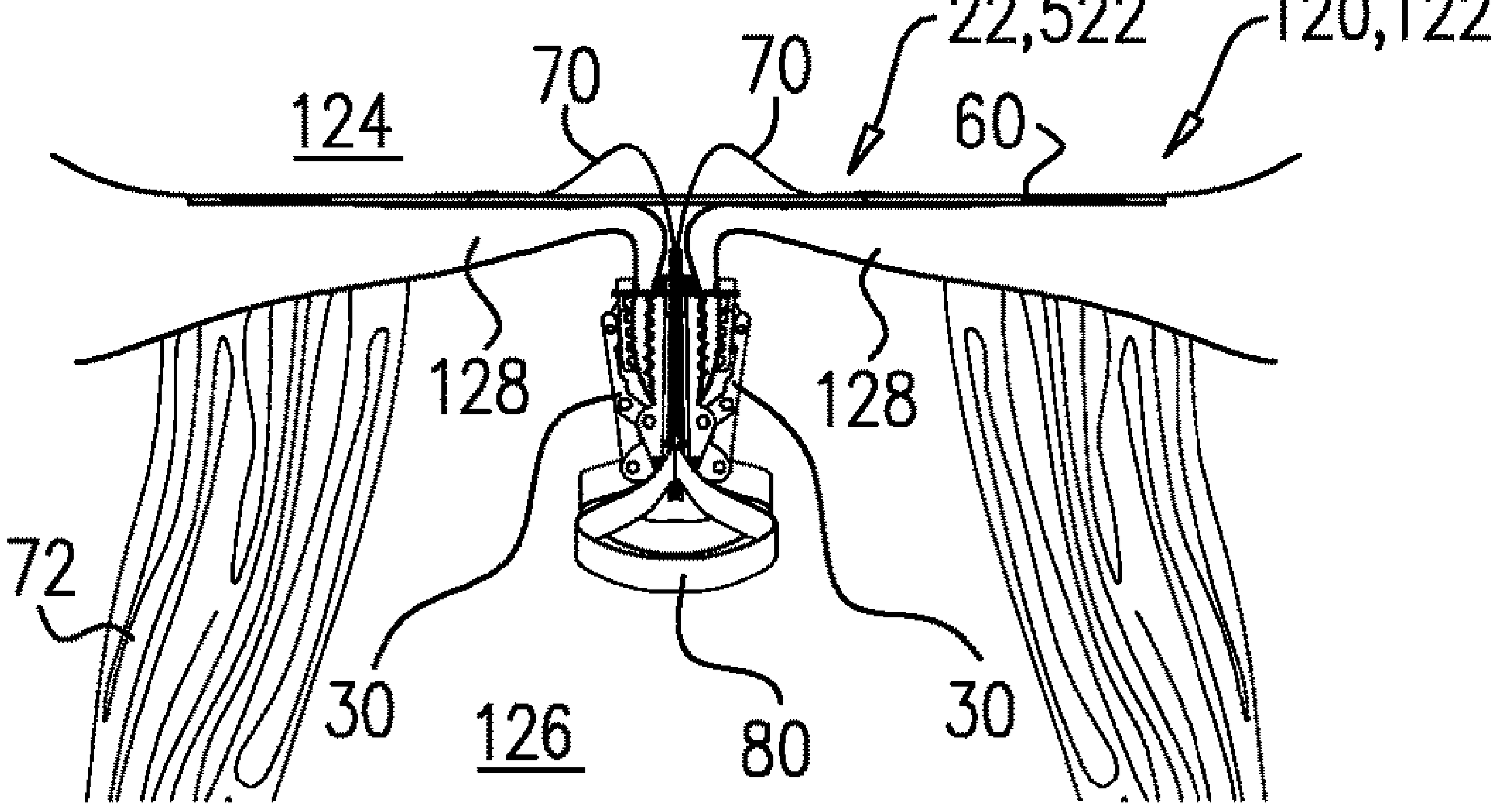



FIG. 6B

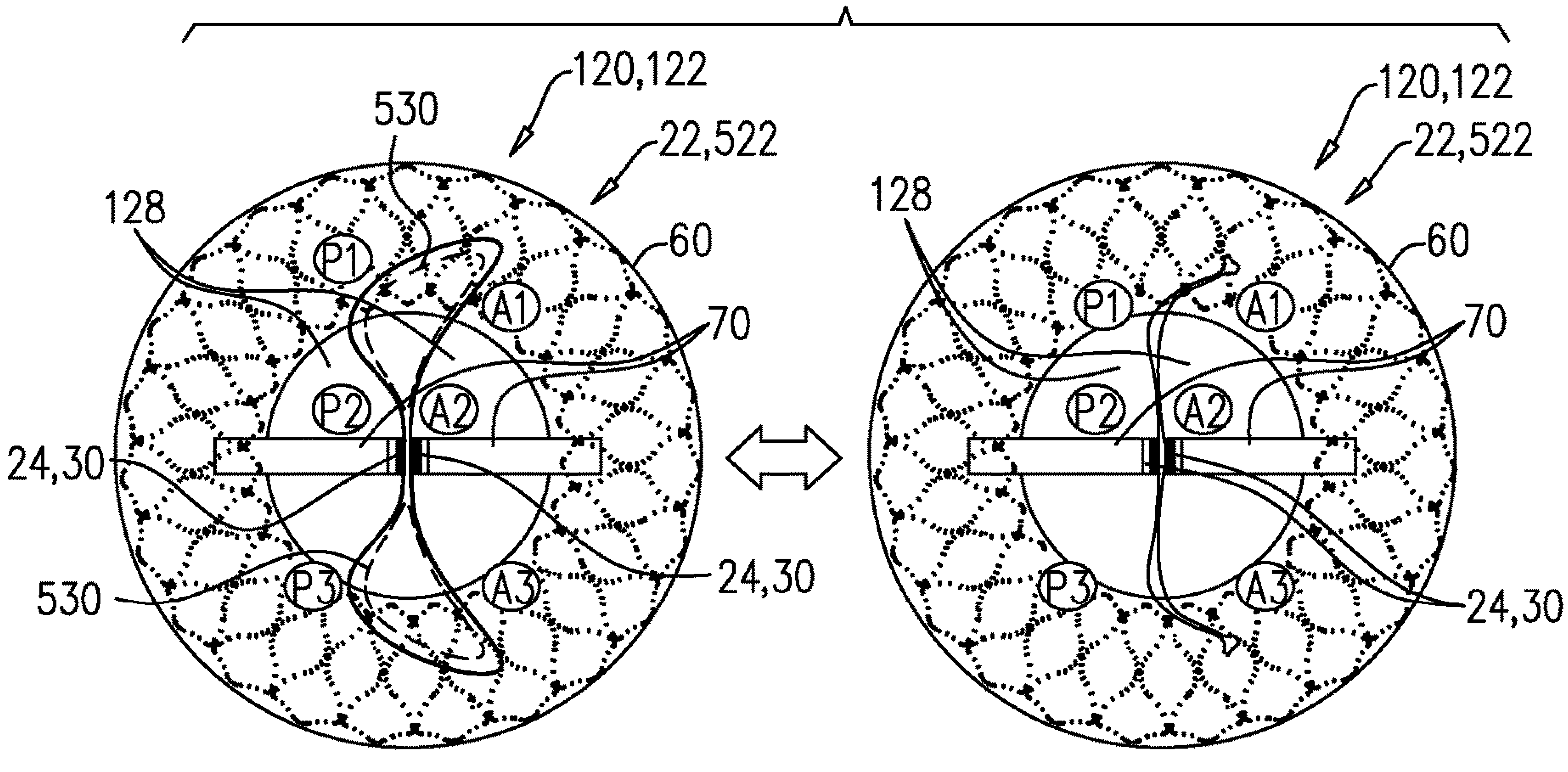


FIG. 7

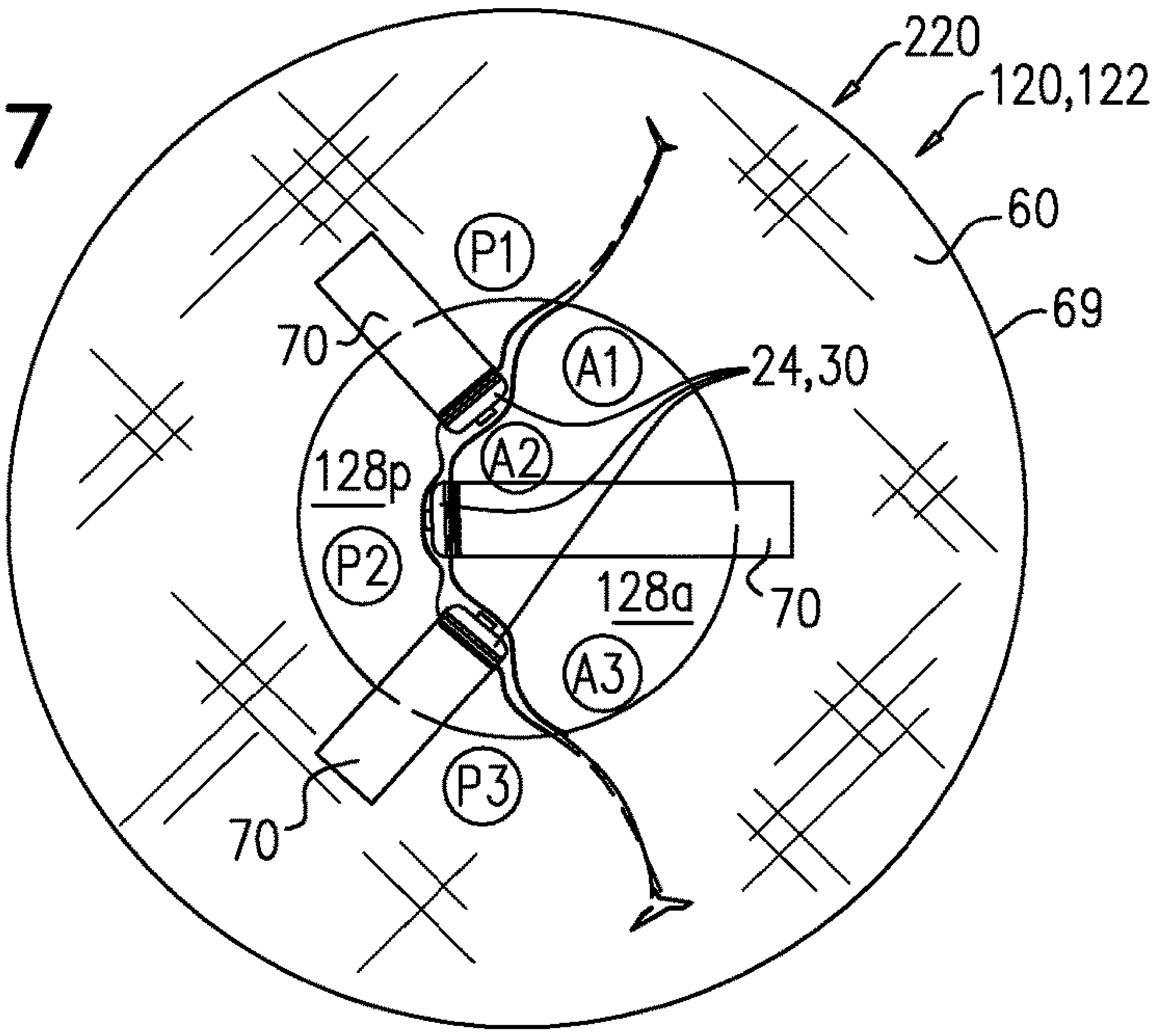

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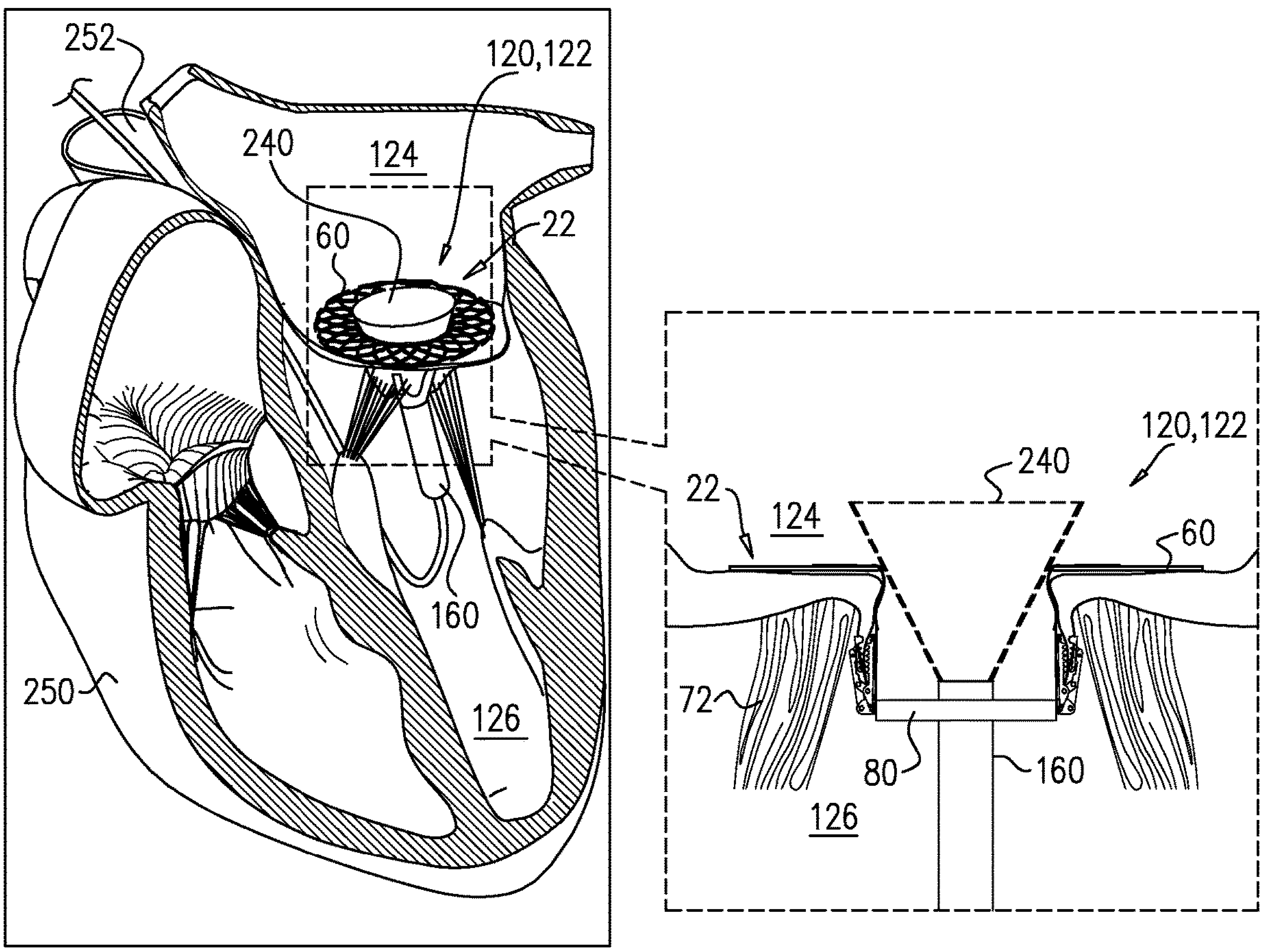
FIG. 8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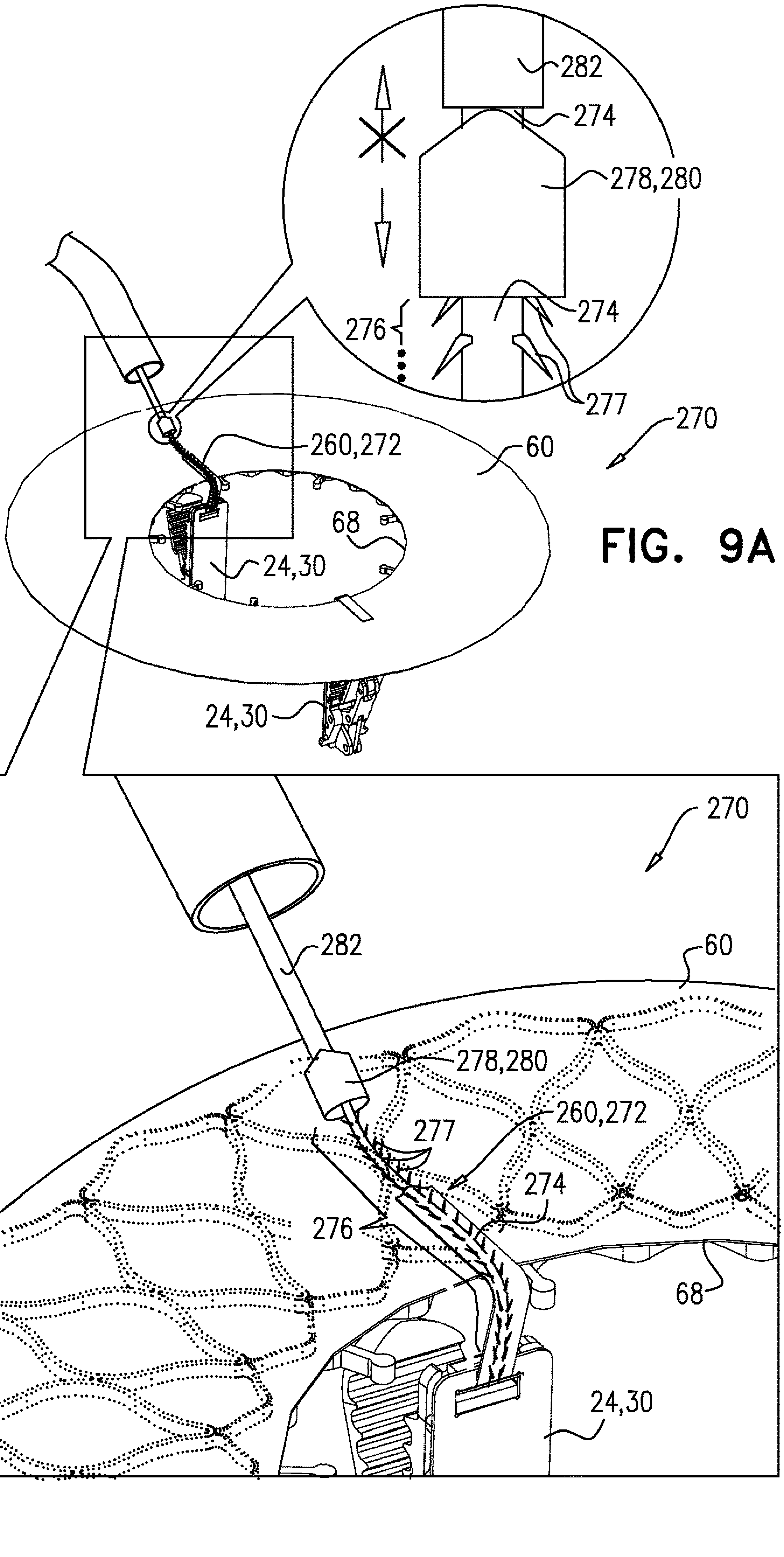
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FIG. 9A

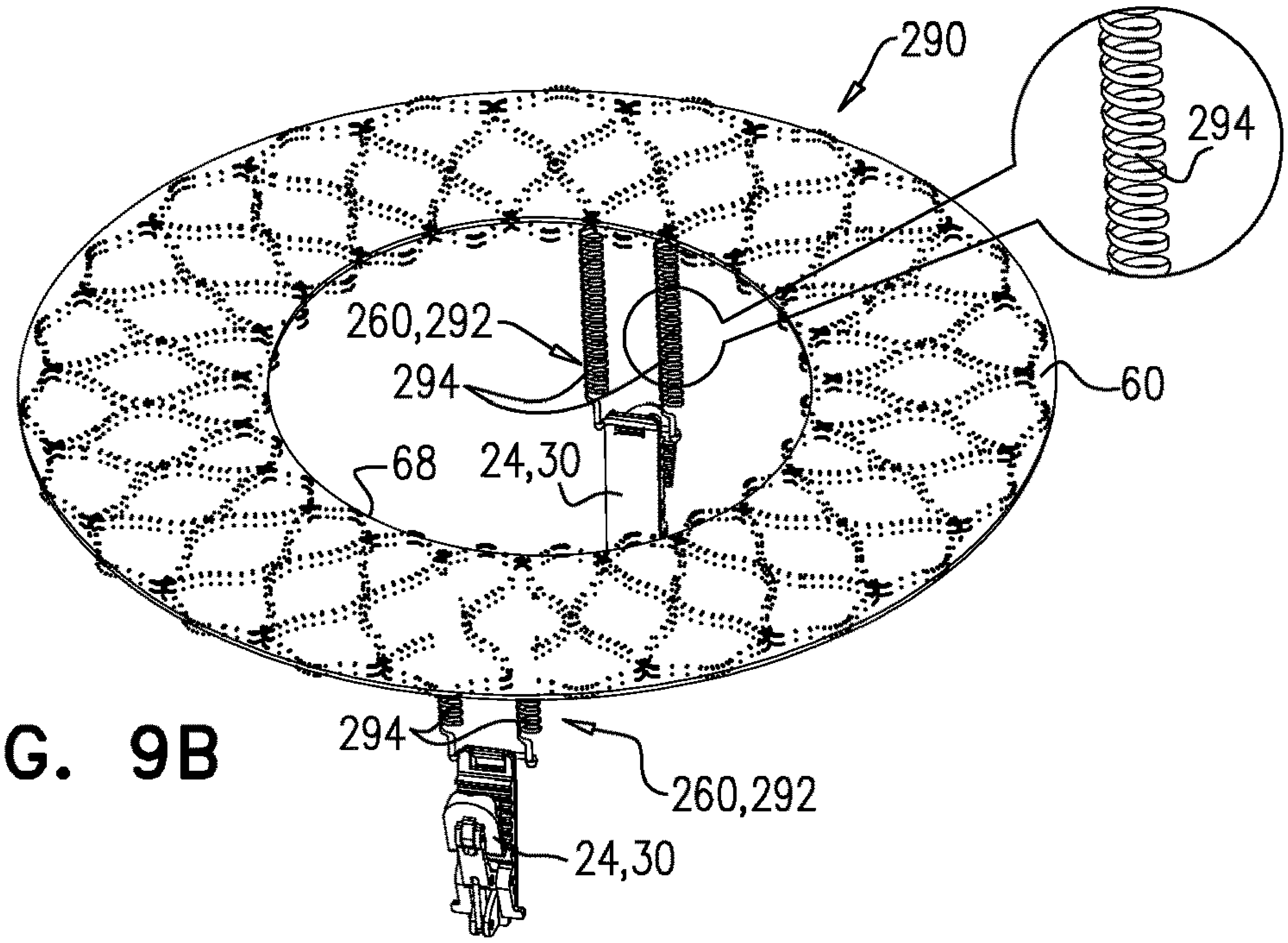
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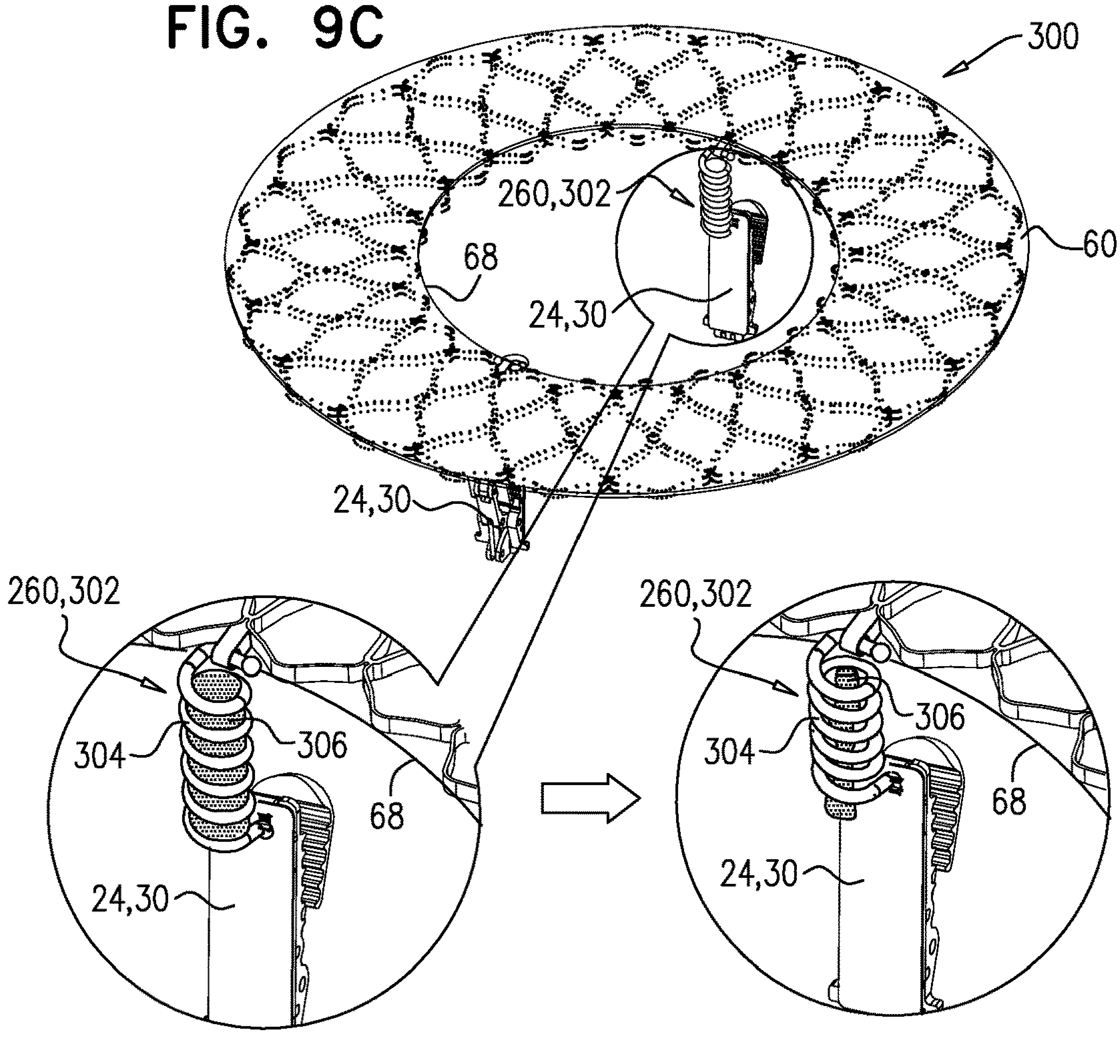
FIG. 9B

FIG. 9C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24,30

# IMPLANT FOR HEART VALVE

## CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a Continuation of U.S. Ser. No. 17/982,897 to Gross et al., filed Nov. 8, 2022, which published as US 2023/0058653, which is a Continuation of U.S. Ser. No. 16/888,210 to HaCohen, filed May 29, 2020, now U.S. Pat. No. 11,517,436, which is a Continuation of U.S. Ser. No. 16/284,331 to HaCohen, filed Feb. 25, 2019, now U.S. Pat. No. 10,702,385, which is a Continuation of U.S. Ser. No. 15/197,069 to Gross et al., filed Jun. 29, 2016, now U.S. Pat. No. 10,226,341, which is a Continuation of U.S. Ser. No. 14/237,258 to Gross et al., filed May 23, 2014, now U.S. Pat. No. 9,387,078, which is the US National Phase of PCT Patent Application IL2012/000293 to Gross et al., filed Aug. 5, 2012, which published as WO 2013/021375, and which:

(1) claims priority from:

- U.S. 61/515,372 to Gross et al., filed Aug. 5, 2011;
- U.S. 61/525,281 to Gross et al., filed Aug. 19, 2011;
- U.S. 61/537,276 to Gross et al., filed Sep. 21, 2011;
- U.S. 61/555,160 to Gross et al., filed Nov. 3, 2011;
- U.S. 61/588,892 to Gross et al., filed Jan. 20, 2012; and
- U.S. Ser. No. 13/412,814 to Gross et al., filed Mar. 6, 2012, now U.S. Pat. No. 8,852,272, all of which are incorporated herein by reference; and

(2) is a continuation-in-part of U.S. Ser. No. 13/412,814 to Gross et al., filed Mar. 6, 2012, now U.S. Pat. No. 8,852,272.

This application is related to PCT application IL2012/000292 to Gross et al., entitled, "Techniques for percutaneous mitral valve replacement and sealing," filed Aug. 5, 2012, which published as WO 2013/021374.

## FIELD OF THE INVENTION

Some applications of the present invention relate in general to valve replacement. More specifically, some applications of the present invention relate to prosthetic valves for replacement of a cardiac valve.

## BACKGROUND

Ischemic heart disease causes regurgitation of a heart valve by the combination of ischemic dysfunction of the papillary muscles, and the dilatation of the ventricle that is present in ischemic heart disease, with the subsequent displacement of the papillary muscles and the dilatation of the valve annulus.

Dilation of the annulus of the valve prevents the valve leaflets from fully coapting when the valve is closed. Regurgitation of blood from the ventricle into the atrium results in increased total stroke volume and decreased cardiac output, and ultimate weakening of the ventricle secondary to a volume overload and a pressure overload of the atrium.

## SUMMARY OF THE INVENTION

For some applications of the invention, a prosthetic valve support is provided for facilitating minimally invasive (e.g., transcatheter and/or transluminal) implantation of a prosthetic valve at a native valve of a subject. The native valve typically has native check valve functionality, i.e., it functions as a check valve. It is understood that a diseased valve has sub-optimal native check valve functionality, however the term "check valve functionality," as used in the context



of the specification and in the claims, when used with respect to a native valve, refers to the native level of check valve functionality of the native valve. The prosthetic valve support is typically couplable to the native valve (e.g., to leaflets thereof) of the subject without eliminating the check valve functionality of the native valve. The prosthetic valve is subsequently implanted at the native valve by coupling the prosthetic valve to the prosthetic valve support, typically by expanding the prosthetic valve within one or more openings defined by the prosthetic valve support. The implantation of the prosthetic valve at the native valve replaces, at least in part, the check valve functionality of the native valve with substitute check valve functionality of the prosthetic valve. The prosthetic valve support comprises tissue-engaging elements, such as clips. Typically, but not necessarily, the prosthetic valve support further comprises (1) an upstream support portion, configured to be placed against an upstream surface of the native valve, and shaped to define one of the openings, and (2) a stabilizing element, shaped to define another of the openings.

For some applications, the prosthetic valve support is configured to be coupled to the native valve (e.g., to leaflets thereof) without eliminating the check valve functionality of the native valve, by allowing (1) the native leaflets to define a single orifice, and (2) the native valve to function as a single check valve (e.g., to function in a manner that is generally similar to the natural (e.g., physiological) function of the native valve). For some applications, the prosthetic valve support is configured to be coupled to the native valve (e.g., to leaflets thereof) without eliminating the check valve functionality by coupling together respective portions of two leaflets, such that (1) the native leaflets define two orifices, and (2) the native valve functions as two (e.g., parallel) check valves.

For some applications, it is hypothesized that the use of a two-component implant (i.e., comprising the prosthetic valve support and a separate prosthetic valve), advantageously facilitates delivery of the prosthetic valve via a catheter narrower than 28 Fr (e.g., by allowing the use of a 'minimalistic' prosthetic valve, such as a prosthetic valve with few or no appendages).

For some applications, it is hypothesized that the use of a prosthetic valve support that does not eliminate check valve functionality of the native valve, facilitates the separate delivery of the prosthetic valve support and the prosthetic valve (i.e., a two-stage delivery), and thereby further facilitates the use of a narrow catheter.

For some applications, it is further hypothesized that the use of the prosthetic valve support enhances the check valve functionality of the native valve, and thereby provides both (1) "repair" of the native valve, and (2) an implantation site that is pre-prepared for subsequent implantation of a prosthetic valve at a later date, should such implantation be subsequently considered necessary.

There is therefore provided, in accordance with an application of the present invention, apparatus for use with a prosthetic valve for implantation at a native valve of a subject, the native valve including at least one native leaflet, the apparatus including:

a prosthetic valve support, including:

an upstream support portion, being configured to be placed against an upstream side of the native valve, and having an inner perimeter that defines an opening that is configured to receive the prosthetic valve, and

at least one clip:

including at least two clip arms and a clip-controller interface, the clip-controller interface being coupled to at least one of the clip arms, and

being configured to be coupled to a native leaflet of the native valve; and

at least one clip controller, reversibly couplable to the clip-controller interface, and configured to facilitate opening and closing of the clip.

In an application, the at least two clip arms include a first clip arm, configured to be disposed against an upstream surface of the leaflet, and a second clip arm, configured to be disposed against a downstream surface of the leaflet.

In an application, the clip controller is configured to facilitate opening and closing of the clip irrespective of a state of expansion of the prosthetic valve support.

In an application, the at least one clip includes at least a first clip and a second clip, and the second clip is openable and closeable independently of the first clip.

In an application, the at least one clip includes at least a first clip and a second clip, and the first clip is fixedly coupled to the second clip, and is configured to be decoupled from the second clip.

In an application, the at least one clip is configured to be coupled to a single native leaflet of the native valve.

In an application, the at least one clip is configured to be lockable such that the first clip arm is locked with respect to the second clip arm.

In an application:

the native valve includes at least a first native leaflet and a second native leaflet,

the at least one clip includes at least a first clip and a second clip, the first clip being configured to be coupled to the first leaflet, and the second clip being configured to be coupled to the second leaflet, and

the prosthetic valve support is configured such that, when (1) the upstream support portion is disposed against the upstream side of the native valve, (2) the first clip is coupled to the first leaflet, and (3) the second clip is coupled to the second leaflet, the first clip moves toward the second clip during ventricular systole of the subject, and moves away from the second clip during ventricular diastole of the subject.

In an application, the clip is flexibly coupled to the upstream support portion.

In an application, the clip is coupled to the upstream support portion via a flexible connector, the flexible connector having a length from the upstream support portion to the clip, and the length of the flexible connector is variable.

In an application, the upstream support portion is generally flat.

In an application, the inner perimeter defines the opening, such that the opening has a depth and a width, and the width of the opening is more than four times greater than the depth of the opening.

In an application, the upstream support portion has a free inner edge, and the free inner edge defines the inner perimeter.

In an application, the inner perimeter defines an opening that has a diameter, and the upstream support portion has a diameter that is at least 10 percent greater than the diameter of the opening.

In an application, no part of the prosthetic valve support that circumscribes a space that has a perimeter greater than 60 mm has a height of more than 20 mm.

There is further provided, in accordance with an application of the present invention, apparatus for facilitating implantation of a prosthetic valve at a native heart valve of a subject, the native heart valve including a native annulus and a plurality of native leaflets that provide check valve functionality, the apparatus including a prosthetic valve support, the prosthetic valve support:

being configured to be transluminally-delivered to the native valve and to be deployed at the native valve, and

including one or more tissue-engaging elements, configured to couple the prosthetic valve support to the native leaflets without eliminating the check valve functionality.

In an application, the tissue-engaging elements are configured to couple the prosthetic valve support to the native leaflets without eliminating the check valve functionality, by coupling the prosthetic valve support to the native leaflets such that:

the native leaflets define a single orifice therebetween, and

the native valve functions as a single check valve.

In an application, the tissue-engaging elements include at least a first tissue-engaging element and a second tissue-engaging element, and the first tissue-engaging element is transluminally controllable independently of the second tissue-engaging element.

In an application, the tissue-engaging elements are configured to couple the prosthetic valve support to the native leaflets without eliminating the check valve functionality, by coupling the prosthetic valve support to the native leaflets such that:

the native leaflets define two orifices therebetween, and

the native valve functions as two check valves.

In an application:

the native leaflets include a first leaflet and a second leaflet,

the tissue-engaging elements include at least a first tissue-engaging element and a second tissue-engaging element,

the first tissue-engaging element is configured to be coupled to a portion of the first leaflet, and

the second tissue-engaging element is configured to be coupled to a portion of the second leaflet and to the first tissue-engaging element.

In an application, the apparatus is configured such that the first tissue-engaging element is transluminally, intracorporeally decouplable from the second tissue-engaging element.

In an application, the prosthetic valve support includes an annular upstream support portion:

shaped to define an opening therethrough,

coupled to the tissue-engaging elements,

configured to be placed against an upstream surface of the native annulus, and

configured to be transluminally, intracorporeally, coupled to the prosthetic valve.

In an application, the apparatus further includes the prosthetic valve, and the prosthetic valve includes a flexible netting at at least an upstream portion of the prosthetic valve, and the netting is configured to facilitate coupling of the prosthetic valve to the upstream support portion.

In an application, the prosthetic valve support includes one or more flexible connectors, and each tissue-engaging element is flexibly coupled to the upstream support portion by a respective flexible connector.

In an application, each flexible connector has a length, and is configured such that the length is variable while the tissue-engaging elements are coupled to the native leaflets.

In an application, the upstream support portion has a compressed configuration and an expanded configuration, and is configured (1) to be delivered to the native valve in the compressed configuration, and (2) to be expanded into the expanded configuration at the native valve.

In an application, the apparatus further includes one or more coupling leads, and the apparatus is configured such that the expansion of the upstream support portion is controllable using the coupling leads.

In an application, each coupling lead passes around at least a portion of the upstream support portion, and the apparatus is configured such that the upstream support portion is recompressible from the expanded configuration toward the compressed configuration, by pulling on the coupling leads.

In an application, the prosthetic valve support includes a downstream stabilizing element:

shaped to define an opening therethrough,

coupled to the tissue-engaging elements,

configured to be placed entirely downstream of the native annulus, and

configured to be coupled to the prosthetic valve.

In an application, the apparatus further includes the prosthetic valve, and the prosthetic valve includes a valve body and one or more valve-anchoring elements, the valve-anchoring elements being configured to sandwich the downstream stabilizing element between the valve-anchoring elements and the valve body.

In an application, the prosthetic valve support is configured to be coupled to the native leaflets such that no portion of the prosthetic valve support is disposed upstream of the native annulus.

In an application, the tissue-engaging elements include clips, each clip including a plurality of clip arms, including at least a first clip arm and a second clip arm, and configured to couple at least a portion of one of the native leaflets between the first and second clip arms.

In an application, the apparatus further includes a clip controller, configured to be advanced transluminally to the native valve, and each clip includes a clip-controller interface, configured to be reversibly coupled to the clip controller, and to facilitate extracorporeal control of the clips independently of deployment of the prosthetic valve support.

In an application, each clip is configured such that movement of at least a portion of the clip-controller interface by a first distance, changes a distance between a portion of the first clip arm and a portion of the second clip arm by a second distance that is more than 1.5 times greater than the first distance.

In an application, the tissue-engaging elements are configured to suturelessly couple the prosthetic valve support to the native leaflets.

In an application, the prosthetic valve support is configured to be transluminally, intracorporeally, couplable to the prosthetic valve.

There is further provided, in accordance with an application of the present invention, a method for use at a native valve of a subject, the native valve including at least one native leaflet that provides native check valve functionality, the method including:

transluminally delivering a prosthetic valve support to the native valve;

coupling a prosthetic valve support to the leaflet of the native valve without eliminating the native check valve functionality; and

subsequently, replacing, at least in part, the native check valve functionality with a substitute check valve functionality, by coupling a prosthetic valve to the prosthetic valve support.

In an application:

the prosthetic valve support includes at least one clip,

the clip includes two or more clip arms and a clip-controller interface, and

coupling the prosthetic valve support to the leaflet includes changing an angular disposition between the clip arms by moving the clip-controller interface.

There is further provided, in accordance with an application of the present invention, apparatus for use with a native heart valve of a subject, the apparatus including:

a first expandable prosthetic valve component, including a crimpable frame, and configured to be transcatheterally advanceable toward the native valve while the first prosthetic valve component is in a crimped state thereof,

a second expandable prosthetic valve component, including a crimpable frame, and configured to be transcatheterally advanceable toward the native valve, placeable in the native valve while the second prosthetic valve component is in a crimped state thereof, and couplable to the first prosthetic valve component, expansion of the second prosthetic valve component facilitating coupling of the second prosthetic valve component to the first prosthetic valve component; and

one or more tissue-engagement elements, coupled to at least one of the prosthetic valve components, the tissue-engagement elements configured, when the prosthetic valve component is in an expanded state thereof, to extend from the prosthetic valve component, and to inhibit a proximal movement of the prosthetic valve component.

There is further provided, in accordance with an application of the present invention, apparatus for use with a prosthetic valve for implantation at a native valve of a subject, the native valve (1) defining an orifice, (2) including at least one native leaflet, having a native beating, and (3) having a native blood flow regulation functionality, the apparatus including:

a prosthetic valve support, including:

an upstream support portion, configured to be placed against an upstream side of the native valve, to have an inner perimeter that defines an opening that is configured to receive the prosthetic valve, and

at least one clip, configured to be coupled to a native leaflet of the native valve, the clip including a plurality of clip arms, at least one clip arm coupled to a clip-controller interface; and

a clip controller, couplable to the clip-controller interface, and configured to control a relative angular disposition between the clip arms.

For some applications, techniques described herein are practiced in combination with techniques described in one or more of the references cited in the Background section and Cross-references section of the present patent application.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-D are schematic illustrations of apparatus, comprising a prosthetic valve support, for facilitating implantation of a prosthetic heart valve at a native heart valve of a subject, in accordance with some applications of the invention;

FIGS. **2**A-D are schematic illustrations of the prosthetic valve support, and components thereof, in accordance with respective applications of the invention;

FIGS. **3**A-I are schematic illustrations of steps in the delivery and implantation of the prosthetic valve support at the native heart valve of the subject, and the use thereof to facilitate implantation of the prosthetic valve, in accordance with some applications of the invention;

FIGS. **4**A-F are schematic illustrations of a system for facilitating controlled expansion and/or retrievability of an upstream support portion of the prosthetic valve support, in accordance with some applications of the invention;

FIG. **5** is a schematic illustration of a step in the implantation of the prosthetic valve support, in accordance with some applications of the invention;

FIGS. **6**A-B are schematic illustrations of a prosthetic valve support comprising tissue-engaging elements that are couplable to each other, and decouplable from each other, in accordance with some applications of the invention;

FIG. **7** is a schematic illustration of a prosthetic valve support comprising the upstream support portion and three clips, in accordance with some applications of the invention;

FIG. **8** is a schematic illustration of a step in the implantation of the prosthetic valve, facilitated by the prosthetic valve support, in accordance with some applications of the invention; and

FIGS. **9**A-C are schematic illustrations of the prosthetic valve support comprising variable-length connectors, in accordance with respective applications of the invention.

## DETAILED DESCRIPTION OF EMBODIMENTS

Reference is made to FIGS. **1**A-D, which are schematic illustrations of apparatus **20**, comprising a prosthetic valve support **22** for facilitating implantation of a prosthetic heart valve at a native heart valve of a subject, in accordance with some applications of the invention. Prosthetic valve support **22** comprises one or more tissue-engaging elements **24** (e.g., support-anchoring elements), and is typically configured to be coupled to the native heart valve (e.g., to leaflets thereof) without eliminating check valve functionality of the native heart valve (described in more detail hereinbelow). Typically, prosthetic valve support **22** is configured to be transluminally, intracorporeally coupled to the native heart valve.

Typically, each tissue-engaging element **24** comprises a clip **30**, which typically comprises a plurality of clip arms **32** (e.g., two clips arms, e.g., a first clip arm **32***a* and a second clip arm **32***b*), the clip being configured to be coupled to a leaflet of the native valve. Clip arms **32***a* and **32***b* are movable with respect to each other, thereby opening and closing clip **30** (e.g., moving clip **30** between an open state and a closed state thereof), e.g., as shown in FIG. **1**B. Clip arms **32***a* and **32***b* are typically articulatably coupled to each other at an articulation point **31** (e.g., a coupling point), such that opening and closing clip **30** comprises changing a relative angular disposition between the clip arms. Typically, each clip arm **32** has a length from a first end thereof, at which the clip arms are coupled to each other (e.g., at articulation point **31**), to a second end thereof, of greater than 1.5 mm and/or less than 20 mm (e.g., between 3 and 10 mm). For some applications, a length d**7** of clip arm **32***a* is generally the same as a length d**8** of clip arm **32***b* (e.g., as shown in FIG. **1**B). For some applications, length d**8** of clip arm **32***b* is shorter than length d**7** of clip arm **32***a* (e.g., at least 30% shorter, such as at least 50% shorter), e.g., so as to reduce force applied to the leaflet of the native valve by clip arm **32***b* (such as by the second end of the clip arm).

For some applications of the invention, at least one of the clip arms (e.g., clip arm **32***b*) comprises a tissue-engaging portion **48** that is articulatably coupled to another portion of the clip arm at an articulation point **47**, such that, at a given relative angular disposition of clip arms **32***a* and **32***b* (e.g., a degree of openness of clip **30**), a relative angular disposition of portion **48** with respect to clip arm **32***a*, may change (e.g., may be changed). For example, for at least some states of clip **30**, the relative angular disposition of clip arm **32***a* and portion **48** may be generally independent of the relative angular disposition of clip arm **32***a* and the other portion of clip arm **32***b*. For example, portion **48** may remain parallel with clip arm **32***a*, irrespective of the angular disposition of clip arms **32***a* and **32***b*. It is hypothesized that this configuration facilitates coupling of clip **30** to the leaflet of the native valve, by allowing the clip to maintain contact with both sides of the leaflet, irrespective of dimensions (e.g., thicknesses) of the leaflet to which clip **30** is coupled.

Prosthetic valve support **22** is typically configured to be implanted using minimally-invasive procedures (e.g., percutaneously). Further typically, the prosthetic valve support is configured to be delivered transluminally (e.g., transfemorally). Alternatively, the prosthetic valve support may be configured to be delivered transthoracically (e.g., transapically). Typically, the prosthetic valve support is configured in this way by being compressible (e.g., crimpable) into a delivery configuration, and by being configured to expand (e.g., automatically) upon deployment at the native valve. Typically, tissue-engaging elements **24** (e.g., clips **30**) are coupled to the leaflets of the native valve before prosthetic valve support **22** is fully deployed, such as while at least part of the prosthetic valve support remains within a delivery tube (e.g., as shown in FIGS. **3**B-C).

Clips **30** are typically configured to be controllable (i.e., openable and closable) independently of each other, and/or independently of deployment of prosthetic valve support **22** (e.g., irrespective of a state of deployment of the prosthetic valve support, such as irrespective of a state of expansion of an upstream support portion **60** of the prosthetic valve support, described hereinbelow).

Clip **30** typically further comprises a clip-controller interface **34**, which is configured to facilitate control (e.g., opening and closing) of the clip from outside the subject (i.e., to facilitate extracorporeal control of the clip), e.g., by a physician. Clip-controller interface **34** is reversibly couplable to a clip controller **36**, which is itself extracorporeally controllable, e.g., by extending from outside the subject to the clip-controller interface. Clip **30** is thereby typically transluminally controllable. Typically, clip controller **36** facilitates control of the clip by applying a force to clip-controller interface **34**, e.g., by transferring an extracorporeally-applied force to the clip-controller interface. Typically, clip controller **36** is integral with delivery apparatus that is used to deliver support **22** to the native valve (e.g., delivery apparatus **140**, described hereinbelow with reference to FIGS. **3**A-D).

Clip-controller interface **34** is typically articulatably coupled to at least clip arm **32***b* (e.g., at an articulation point **35**), and/or comprises one or more articulatably coupled portions (e.g., a first interface portion **34***a* and a second interface portion **34***b*). Clips **30** are typically configured such that movement of clip-controller interface **34** by a first distance d**1**, moves clip arm **32***b* by a second distance d**2** that is typically more than 1.5 times (e.g., more than 2 times, such as more than 4 times) greater than distance d**1**. That is, a relatively large range of movement of clip arm **32***b* is provided by a relatively small range of movement of clip-controller interface **34**, e.g., clip-controller interface **34**, clip arm **32***b*, and/or the coupling therebetween, acts as a lever. Clip **30** is typically configured such that clip arm **32***b* can articulate over more than 60 degrees, e.g., more than 100 degrees, such as up to 180 degrees, around articulation point **31**, with respect to clip arm **32***a*.

It is hypothesized that, for some applications, angles of articulation greater than 80 degrees (e.g., greater than 120 degrees, such as up to 180 degrees) facilitate (1) repeated coupling to, and decoupling from, the native leaflets (e.g., multiple attempts to couple to the native leaflets), and (2) retrieval of the clips and/or the entire prosthetic valve support (e.g., into a delivery tube).

Clip-controller interface **34** (e.g., portion **34***a* thereof) is typically slidably coupled to at least clip arm **32***a*. That is, moving of clip-controller interface **34** typically includes sliding of the clip-controller interface with respect to clip arm **32***a* (e.g., by using clip controller **36**).

For some applications of the invention, at least one of clip arms **32** comprises or defines grips **38** and/or teeth **40**, which are configured to facilitate coupling of clip **30** to a native leaflet of the native valve. Typically, grips **38** are configured to atraumatically grip the leaflet and teeth **40** are configured to grip, fold around, and/or pierce the leaflet. For some applications of the invention, at least a portion of clip arms **32** is covered with a padding (not shown), configured to cushion the contact between the clip arms and the leaflet.

Typically, clip **30** is lockable, such that clip arm **32***b* is locked (e.g., immobile) with respect to clip arm **32***a*. FIGS. **1**B-D show clip **30** comprising a locking element **50** (e.g., a securing element), which facilitates locking of the clip. Locking element **50** typically comprises at least one ratchet mechanism **52**, comprising (1) a rack **51**, comprising a plurality of sockets **54**, and (2) an engaging element **56** (e.g., a pawl, or a tooth). Typically, rack **51** is defined by, or is fixedly coupled to, clip arm **32***a*, and engaging element **56** is coupled to, or defined by, clip-controller interface **34**. However, the scope of the invention includes other (e.g., inverse) arrangements of ratchet mechanism **52**.

FIG. **1**B shows clip **30** in an unlocked configuration thereof, in which an obstructing element **58** (e.g., a restraint) is disposed between rack **51** and engaging element **56**, thereby inhibiting (e.g., obstructing) engaging element **56** from engaging rack **51**, and thereby facilitating the opening and closing of the clip (i.e., movement between open and closed states thereof). Typically, obstructing element **58** is integral with delivery apparatus that is used to deliver support **22** to the native valve (e.g., delivery apparatus **140**, described hereinbelow with reference to FIGS. **3**A-D). FIG. **1**B shows a front view and a back view of clip **30** in the open state thereof, and a front view and a back view of the clip in the closed state thereof.

FIG. **1**C shows a back view of clip **30** in a locked configuration thereof, in which obstructing element **58** has been removed from between rack **51** and engaging element **56** (e.g., by withdrawing the obstructing element proximally), and an engaging element **56** has engaged the rack. Typically, element **56** is configured (e.g., shape-set) to automatically engage rack **51** upon removal of obstructing element **58**.

For some applications, and as shown in FIGS. **1**B-D, obstructing element **58** comprises a longitudinal member, such as a strip or rod, and is removed by being withdrawn proximally. However, obstructing element **58** may have other shapes and/or shape-memory features that facilitate the obstruction of engaging element **56** and/or the removal of the obstructing element. For example, obstructing element **58** may have a generally circular, rectangular, triangular, or hexagonal cross-section, and/or may be shape-set to facilitate removal thereof, and thereby to facilitate locking of the clip.



For some applications of the invention, and as shown in FIGS. **1**B-D, locking element **50** comprises two ratchet mechanisms **52**. The two ratchet mechanisms are offset with respect to the other, such that at a position of clip-controller interface **34** in which the engaging element **56** of one ratchet mechanism is fully disposed in a socket **54**, the engaging element of the other ratchet mechanism is not fully disposed in a socket of the other rack (FIGS. **1**C-D). This configuration increases (e.g., doubles) the number of positions within a given range in which clip-controller interface **34** is lockable, without reducing the size of each socket **54**. That is, this configuration increases the "resolution" or "density" of locking positions of clip **30**. It is hypothesized that, for some applications, it is advantageous to combine this configuration of locking element **50** with the lever-like clip-controller interface described hereinabove, such that the relatively large movement of clip arm **32***b* is at least partly offset by the "high resolution" of the locking element, thereby increasing the degree of control that the physician has on the clip.

As described hereinabove, clip-controller interface **34** is typically reversibly couplable to clip controller **36**. Typically, this reversible coupling is facilitated by a projection **42**, defined by clip controller **36**, which is configured to be disposed within, and removed from, a depression **44**, defined by clip-controller interface **34**. Further typically, projection **42** is configured (e.g., shape-set) to move out from depression **44**, and is prevented from moving out of depression **44** by obstructing element **58**. Following the locking of clip **30** by withdrawing obstructing element **58** (FIG. **1**C), the obstructing element is further withdrawn (FIG. **1**D), thereby releasing projection **42** from depression **44**, and thereby decoupling clip controller **36** from clip-controller interface **34**. Clip **30** is typically configured such that the physician may repeatedly lock and unlock clip **30** (e.g., by partially withdrawing and replacing obstructing element **58**) before finally decoupling the controller (e.g., by completely withdrawing obstructing element **58**), such as after confirming that clip **30** has been successfully coupled to the native leaflet.

As described hereinabove, clips **30** are typically configured to be controllable (i.e., openable and closable) independently of each other, and/or independently of deployment of prosthetic valve support **22**. Clips **30** are further typically lockable and/or decouplable from controller **36** independently of each other, and/or independently of deployment of the prosthetic valve support. It is to be noted that clips **30** are configured to couple the prosthetic valve support to the native leaflets suturelessly.

Referring again to FIG. **1**A, prosthetic valve support **22** typically comprises a generally annular upstream support portion **60** (e.g., an annular portion), shaped to define an opening **61** (e.g., an aperture) therethrough, and to be placed against an upstream side of the native valve. Typically, upstream support portion **60** comprises an expandable lattice-structure frame **62** (e.g., comprising a plurality of struts), covered by a covering **64**. Opening **61** is defined by an inner perimeter **68** of the prosthetic valve support. For some applications, frame **62** defines a plurality of barbs **67** that protrude radially inwardly from inner perimeter **68**, and facilitate coupling of a prosthetic valve to the prosthetic valve support (e.g., as described hereinbelow with reference to FIGS. **3**H-I).

Upstream support portion **60** typically has shape-memory (e.g., resilient, pseudoelastic and/or superelastic) properties. Typically, frame **62** comprises a shape-memory (e.g., resilient, pseudoelastic and/or superelastic) material, such that upstream support portion **60** is compressible (e.g., crimpable) when a compressive force is applied (e.g., prior to implantation), and re-expandable when the compressive force is removed (e.g., during implantation). Non-limiting examples of materials that frame **62** may comprise, include nickel-titanium (nitinol), stainless steel, nickel cobalt, cobalt chrome, titanium, tantalum, and palladium.

Non-limiting examples of materials that covering **64** may comprise, include polyethylene terephthalate (e.g., polyester), polytetrafluoroethylene (e.g., Teflon, ePTFE), and pericardial tissue. For some applications, covering **64** comprises a fabric. Typically, a thickness of the covering is less than 0.5 mm, such as less than 0.2 mm, e.g., less than 0.1 mm, or less than 0.05 mm.

FIG. **1**A shows upstream support portion **60** in an expanded (e.g., fully uncompressed and/or deployed) configuration thereof, in which upstream support portion **60** (i.e., an outer perimeter **69** thereof) typically has a diameter d**3** that is greater than 40 mm and/or less than 80 mm (e.g., 40-80 mm, such as 40-70 mm, such as 40-60 mm). That is, an outer diameter of upstream support portion **60** is typically greater than 40 mm and/or less than 80 mm (e.g., 40-80 mm, such as 40-70 mm, such as 40-60 mm). Opening **61**, defined by inner perimeter **68**, typically has a diameter d**4** of greater than 20 mm and/or less than 35 mm (e.g., 20-35 mm, such as 23-32 mm, such as 25-30 mm). That is, an inner diameter of upstream support portion **60** is typically greater than 20 mm and/or less than 35 mm (e.g., 20-35 mm, such as 23-32 mm, such as 25-30 mm). Typically, diameter d**3** is at least 10% (e.g., at least 50%, such as at least 80%) greater than diameter d**4**.

Upstream support portion **60** is typically compressible (e.g., crimpable; for delivery to the native valve) into a generally cylindrical shape in which inner perimeter **68** defines a downstream end **71** of the cylindrical shape, and outer perimeter **69** defines an upstream end **73** of the cylindrical shape (see FIG. **3**A). Typically, the generally cylindrical shape of upstream support portion **60** has a transverse cross-sectional diameter (e.g., a width) of greater than 3 mm and/or less than 9 mm (e.g., 3-9 mm, such as 5-8 mm, such as 6-7 mm), and a height, from the upstream end to the downstream end, of greater than 11 mm and/or less than 30 mm (e.g., 11-30 mm, such as 15-30 mm, such as 15-25 mm).

In the expanded configuration thereof, upstream support portion **60** is typically (but not necessarily) generally flat (e.g., laminar, and/or planar). For some applications, in the expanded configuration, upstream support portion **60** assumes a frustoconical shape. Upstream support portion **60** typically has a thickness of less than 5 mm, e.g., less than 2 mm, such as between 0.3 mm and 2 mm. Inner perimeter **68** (and thereby opening **61**) thereby typically has a depth d**10** (e.g., a height) from an upstream side **59** of the upstream support portion to a downstream side **63** of the upstream support portion. Depth d**10** is less than 5 mm, e.g., less than 2 mm, such as between 0.3 mm and 2 mm. Typically, diameter d**4** of opening **61** is more than 4 times (e.g., more than 6 times, such as more than 10 times) greater than depth d**10**. That is, opening **61** is more than 4 times (e.g., more than 6 times, such as more than 10 times) wider than it is deep. Typically, in the expanded configuration, upstream support portion **60** has a total height of less than 10 mm (e.g., less than 5 mm, such as less than 2 mm).

Typically, inner perimeter **68** comprises, or is defined by, a free inner edge of upstream support portion **60**. That is, opening **61** resembles a hole cut out of a lamina (e.g., out of a disc). For some applications, inner perimeter **68** comprises, or is defined by, a curved and/or folded inner edge of upstream support portion **60**. If the inner perimeter of upstream support portion **60** comprises, or is defined by, a curved or folded edge, then a radius of curvature of the curved or folded edge is typically less than 2.5 mm, such as less than 1 mm. That is, the curve or fold of the edge is generally sharp, such that when viewed from within opening **61**, the curved or folded edge looks generally like a free edge.

Prosthetic valve support **22** typically comprises two or more tissue-engaging elements **24** (e.g., clips **30**), coupled to inner perimeter **68** of upstream support portion **60**. For such applications, the two tissue-engaging elements are typically disposed opposite each other (e.g., at 180 degrees around inner perimeter **68** from each other).

Typically, tissue-engaging elements **24** (e.g., clips **30**) are coupled to upstream support portion **60** (e.g., inner perimeter **68** thereof) by a flexible connector **70**, which may comprise polyethylene terephthalate (e.g., polyester), polytetrafluoroethylene (e.g., Teflon, ePTFE), a fabric, nitinol, and/or any other suitable material. Thereby, tissue-engaging elements **24** (e.g., clips **30**) are typically flexibly coupled to upstream support portion **60**, and/or are able to move independently of each other. Connector **70** may be coupled to upstream support portion **60** and tissue-engaging elements **24** using sutures, welding, and/or any other suitable technique known in the art.

Prosthetic valve support **22** typically further comprises a stabilizing element **80**, coupled to clips **30** (e.g., to a downstream portion thereof). Typically, stabilizing element **80** forms a ring shape that defines an opening **81** (e.g., an aperture), and is typically inelastic and at least partly flexible. Opening **81** typically, but not necessarily, has a diameter that is generally equal to diameter d**4** of opening **61**. Non-limiting examples of materials that stabilizing element **80** may comprise include polyethylene terephthalate (e.g., polyester), PTFE (e.g., ePTFE), nylon, cotton, nitinol, stainless steel, nickel cobalt, cobalt chrome, titanium, tantalum and palladium. Typically, and as shown in FIG. **1**A, stabilizing element **80** comprises (1) an outer coat **82** of a flexible material (e.g., polyester), which typically provides inelasticity, and (2) an inner strip **84** of a shape-memory material (e.g., nitinol), which is typically configured (e.g., shape-set) to bias element **80** to assume a ring-shaped configuration.

Stabilizing element **80** (and thereby opening **81**) typically has a depth d**11** (e.g., a height from a most upstream part to a most downstream part) of less than 20 mm (e.g., less than 10 mm, e.g., less than 5 mm, such as less than 1 mm). As described hereinabove, inner perimeter **68** of upstream support portion has a depth d**10** of less than 5 mm. Typically, in the expanded configuration, no part of prosthetic valve support **22** that circumscribes a space that has a perimeter greater than 60 mm (e.g., as upstream support portion **60** and stabilizing element **80** typically do) has a height of more than 20 mm. For some applications, in the expanded configuration, no part of the support that circumscribes a space that has a perimeter greater than 60 mm has a height of more than 10 mm. For some applications, in the expanded configuration, no part of the support that circumscribes a space that has a perimeter greater than 60 mm has a height of more than 5 mm.

Reference is made to FIGS. **2**A-D, which are schematic illustrations of prosthetic valve support **22** and/or components thereof, in accordance with respective applications of the invention. As described hereinabove, upstream support portion **60** is generally annular. For some applications, and as shown in FIG. **1**A, upstream support portion **60** has a generally circular outer perimeter **69**. FIG. **2**A shows an alternative embodiment in which upstream support portion **60** comprises an upstream support portion **90**, which has a non-circular outer perimeter **99**. FIG. **2**A shows outer perimeter **99** as generally oval, with a "squashed" portion **92**. Such a configuration may, for example, facilitate placement of upstream support portion **90** at a mitral valve of the subject, with squashed portion **92** facing the interatrial septum. It is to be noted, that the scope of the invention includes upstream support portions having other shapes, configured according to the anatomical site at which they are to be placed. For example, for some applications, upstream support portion **60** and/or upstream support portion **90** may have radially-protruding bulges or wings (not shown), configured to stabilize the upstream support portion and/or to inhibit leakage between the native valve and the upstream support portion.

As described hereinabove, upstream support portion **60** typically comprises an expandable lattice-structure frame **62**. FIG. **2**B shows an alternative embodiment in which upstream support portion **60** comprises a braided upstream support portion **100**, which comprises a braided structure of intertwining strands **102**, at least some of which are slidable past (e.g., over, under) each other. Typically, strands **102** comprise a shape-memory material such as, but not limited to, nitinol. Upstream support portion **100** is transluminally deliverable in a compressed configuration, and is expandable to an annular, expanded configuration at the native valve. Typically, support **100** is configured to automatically expand to the expanded configuration, and this expansion is controlled by progressively releasing (e.g., loosening and/or unthreading) a restricting element **104** (e.g., a drawstring), which, when threaded through parts of upstream support portion **100** (e.g., one or more rings **106** thereof), is configured to restrict expansion of the upstream support portion (e.g., to retain the upstream support portion in the compressed configuration thereof). FIG. **2**B shows sequential stages in the deployment of upstream support portion **100** from a delivery tube **108**. Typically, upstream support portion **100** is recompressible by tightening (e.g., pulling) the restricting element.

As described hereinabove, prosthetic valve support **22** comprises one or more tissue-engaging elements **24**, and typically further comprises upstream support portion **60** and/or stabilizing element **80**. FIG. **1**A shows prosthetic valve support **22** comprising both upstream support portion **60** and stabilizing element **80**. FIG. **2**C shows an alternative embodiment in which prosthetic valve support **22** comprises a prosthetic valve support **322**, which does not comprise stabilizing element **80**. FIG. **2**D shows an alternative embodiment in which prosthetic valve support **22** comprises a prosthetic valve support **422**, which does not comprise an upstream support portion (e.g., upstream support portion **60**). For some applications of the invention, when implanted at the native valve, no portion of prosthetic valve support **422** is disposed upstream of the native annulus.

It is to be noted that upstream support portions **90** and **100**, and prosthetic valve supports **322** and **422**, may be used (e.g., combined) with apparatus and methods described elsewhere herein. For example, the upstream support portion of any of the prosthetic valve supports described herein may be replaced with upstream support portion **90** or upstream support portion **100**, resulting in alternative prosthetic valve supports. Furthermore, these resulting prosthetic valve supports, as well as prosthetic valve supports **322** and **422**, may be used in combination with other techniques described herein (e.g., with reference to FIGS. **3**A-I, **4**A-F, **5**, **6**A-B, **7**, **8**, and/or **9**A-C), mutatis mutandis.

Reference is made to FIGS. **3**A-I, which are schematic illustrations of steps in the delivery and implantation of prosthetic valve support **22** at a native heart valve **120** of heart **250** of a subject, and the use thereof to facilitate implantation of a prosthetic valve **150**, in accordance with some applications of the invention. FIGS. **3**A-I show native valve **120** as comprising a mitral valve **122** of the subject, but it is to be noted that the scope of the invention includes the use of prosthetic valve support **22** at other heart valves of the subject.

Mitral valve **122** is disposed between a left atrium **124** and a left ventricle **126** of the subject, and comprises two leaflets **128**. Atrium **124** is upstream of mitral valve **122** and ventricle **126** is downstream of the mitral valve. Prosthetic valve support **22**, in a compressed configuration **30** thereof, is advanced transluminally (e.g., transfemorally and/or transseptally) within a delivery tube **130** of delivery apparatus **140**, to atrium **124**, and between leaflets **128** (FIG. **3**A).

Prosthetic valve support **22** is advanced out of delivery tube **130** and/or the delivery tube is withdrawn from the prosthetic valve support (FIG. **3**B). Clips **30** (and/or other tissue-engaging elements) are typically disposed at a downstream portion of prosthetic valve support **22** (e.g., downstream of downstream end **71** of upstream support portion **60**) in the compressed configuration thereof, and are thereby exposed from delivery tube **130**. Stabilizing element **80** is also typically exposed from the delivery tube, and typically forms a generally lemniscate (e.g., figure-8) shape, defining two "loops" **83**. Typically, the axis between loops **83** of the lemniscate is generally orthogonal to the axis between clips **30**, and may be used to orient prosthetic valve support **22**, e.g., such that clips **30** point toward leaflets **128** of the native valve. For example, loops **83** may be disposed between chordae tendineae **72** of one leaflet and those of the other leaflet, and physical contact between the chordae tendineae and the loops automatically and/or via tactile feedback to the physician, facilitates orientation of the prosthetic valve support. Alternatively or additionally, the lemniscate shape of stabilizing element **80** may be visualized using imaging techniques such as fluoroscopy and/or ultrasound. Clips **30** are opened (e.g., as described hereinabove with reference to FIG. **1**B).

Prosthetic valve support **22** is moved upstream (e.g., proximally) so as to envelope leaflets **128** between clip arms **32** of each clip **30**, and each clip is closed around a leaflet, thereby coupling each clip to a leaflet, e.g., by clamping the leaflet between the clip arms (FIG. **3**C). Each clip **30** couples to a single leaflet **128**, such that one clip arm of each clip (e.g., clip arm **32***a*) engages an upstream surface of the leaflet (e.g., an upstream side of the leaflet), and the other clip arm of each clip (e.g., clip arm **32***b*) engages a downstream surface of the leaflet (e.g., a downstream side of the leaflet). Although each clip typically couples to only one leaflet, for some applications, more than one clip couples to each leaflet.

As described hereinabove, clips **30** (and/or other tissue-engaging elements **24**) are typically coupled to the leaflets of the native valve before prosthetic valve support **22** is fully deployed. Clips **30** are typically locked (e.g., as described with reference to FIG. **1**C), and subsequently decoupled from clip controller **36** (e.g., as described with reference to FIG. **1**D). FIGS. **3**C-F show stages in the deployment of prosthetic valve support **22** (e.g., of upstream support portion **60** thereof). Upstream support portion **60** typically progressively expands as it is exposed from delivery tube

130. Thereby, typically, (1) downstream end **71** of the cylindrical shape of the upstream support portion in the compressed configuration thereof, expands to become inner perimeter **68** of the upstream support portion in the expanded configuration thereof, and (2) subsequently, upstream end **73** of the cylindrical shape expands to become outer perimeter **69** of the upstream support portion.

Delivery apparatus **140** typically comprises a pushing member **132**. Typically, prosthetic valve support **22** (e.g., upstream support portion **60** thereof) is reversibly coupled to pushing member **132**, and is exposed from delivery tube **130** by being pushed using the pushing member. Upstream support portion **60** is typically configured (e.g., shape-set) to automatically expand toward its expanded configuration upon being deployed from delivery tube **130**. For some applications of the invention, the upstream support portion "pops" open from the configuration shown in FIG. **3**C to the configuration shown in FIG. **3**F, immediately upon exposure of upstream end **73** of the upstream support portion from delivery tube **130**.

For some applications, and as shown in FIGS. **3**C-F, one or more holding members **134**, coupled to, and decouplable from, upstream support portion **60**, facilitate controlled expansion of the upstream support portion. For example, holding members **134** may be configured to allow a physician (1) to expand some portions of the upstream support portion before other portions and/or (2) to adjust the positioning of the upstream support portion on the upstream surface of the native valve following expansion of the upstream support portion. For some applications, two holding members **134** are used, and are coupled to opposite sides of upstream support portion **60** to each other (e.g., 180 degrees around the upstream support portion from each other).

For some applications, and as shown in FIGS. **3**D-F, three holding members **134** are used. For such applications, each holding member **134** is coupled at between 90 and 180 degrees (e.g., between 100 and 150 degrees, such as at 120 degrees) around the upstream support portion from the other holding members. For some such applications, and as shown in FIG. **3**F, the holding members are coupled to the upstream support portion such that, when the upstream support portion is positioned at the native valve, two holding members are disposed generally above respective commissures of the native valve, and the third holding member is disposed generally midway around posterior leaflet **128***p* of the native valve.

For some applications, holding members **134** comprise locking elements and/or coupling leads (e.g., coupling wires, e.g., looped around respective portions of the upstream support portion; not shown in FIGS. **3**D-F) that couple the holding members to the upstream support portion, and the holding members are decoupled from the upstream support portion by unlocking the locking elements and/or unlooping the loops. For some applications of the invention, holding members **134** also facilitate retrieval of the upstream support portion, and thereby of prosthetic valve support **22**, e.g., as described with reference to FIGS. **4**A-F.

FIG. **3**G shows prosthetic valve support **22** following coupling, deployment and expansion (i.e., implantation) thereof at mitral valve **122**, and withdrawal of delivery apparatus **140**. As described hereinabove, prosthetic valve support **22** is configured to be coupled to the native heart valve (e.g., to leaflets thereof) without eliminating check valve functionality of the native heart valve. Typically, and as shown in FIG. **3**G, clips **30** couple the prosthetic valve support to leaflets **128** such that (1) the leaflets define a single orifice, and (2) the native valve functions as a single check valve (e.g., functions in a manner that is generally similar to the natural (e.g., physiological) function of the native valve). Stabilizing element **80** is also configured to allow such movement of leaflets **128**, e.g., the stabilizing element is sufficiently flexible to flex in response to the leaflets moving in response to pumping of the heart. FIG. **3**G shows (1) in solid, mitral valve **122** (e.g., leaflets **128**) closed, and the respective state of prosthetic valve support **22**, and (2) in phantom, the mitral valve (e.g., the leaflets) open, and the respective state of the prosthetic valve support.

Thereby, when prosthetic valve support **22** is implanted at an atrioventricular valve of the subject (e.g., mitral valve **122** or a tricuspid valve), clips **30** typically move away from each other during ventricular diastole, and toward each other during ventricular systole. For applications in which prosthetic valve support **22** is implanted at a native semilunar valve of the subject (e.g., an aortic valve or a pulmonary valve), clips **30** typically move toward each other during ventricular diastole, and away from each other during ventricular systole.

Subsequently (e.g., immediately subsequently, or after more than a minute, e.g., after more than 2 minutes, e.g., after more than 5 minutes, such as after more than an hour), a prosthetic valve **150** is transluminally delivered, in a compressed configuration thereof (e.g., within a delivery tube **160**), to the native valve, and implanted at the native valve by coupling the prosthetic valve to prosthetic valve support **22**. Implantation of prosthetic valve **150** replaces check valve functionality of the native valve with a substitute check valve functionality of the prosthetic valve. The substitute check valve functionality is provided by one or more prosthetic check valve elements (e.g., valve members, such as leaflets, a ball, or a disc), such as those known in the art, which the prosthetic valve comprises (not shown).

Typically, and as shown in FIG. **3**H, respective portions of prosthetic valve **150** are placed within opening **61** (defined by upstream support portion **60**) and/or opening **81** (defined by stabilizing element **80**), and are expanded such that the respective portions engage the upstream support portion and the stabilizing element, respectively. Typically, prosthetic valve **150** is configured to automatically expand upon deployment from delivery tube **160**, and radially-expansive force applied by prosthetic valve **150** to upstream support portion **60** and/or stabilizing element **80** facilitates coupling of the prosthetic valve to prosthetic valve support **22**.

FIG. **3**I shows prosthetic valve **150** having been fully deployed and coupled to prosthetic valve support **22**. That is, FIG. **3**I shows an implant **180**, comprising prosthetic valve support **22** and prosthetic valve **150**, having been implanted at native valve **120** (e.g., at mitral valve **122**). Prosthetic valve **150** is described in more detail hereinbelow.

Typically, diameter d**3** of upstream support portion **60** is greater than a diameter d**5** of the native valve (e.g., a diameter of the orifice of the native valve, e.g., an inner diameter of the annulus of the native valve). Further typically, diameter d**4** of opening **61** is smaller than diameter d**5**. When prosthetic valve **150** is expanded within opening **61** of the upstream support portion, a diameter d**6** of the prosthetic valve is typically restricted by the upstream support portion to the same diameter as diameter d**4** of opening **61**. For some applications, contact between prosthetic valve **150** and upstream support portion **60** (e.g., resulting from the radially-expansive force of the valve on the support) couples the prosthetic valve to the prosthetic valve support, and/or inhibits retrograde leakage of blood therebetween.

When implanted at the native valve (e.g., when in respective expanded configurations), a height d**9** of prosthetic valve **150** is typically at least 1.5 times greater (e.g., at least 3 times greater, such as at least 5 times greater) than the total height of upstream support portion **60**. Typically, height d**9** is at least 1.5 times greater (e.g., at least 3 times greater, such as at least 5 times greater) than depth d**10** of opening **61**.

As described hereinabove, upstream support portion **60** is configured to be placed against an upstream side of the native valve. It should be noted, that radial expansion of prosthetic valve **150** against inner perimeter **68** of upstream support portion **60**, thereby typically does not cause the prosthetic valve support to apply a radially-expansive force to the native valve annulus. For some applications of the invention, this expansion of prosthetic valve **150** does not cause the prosthetic valve support to apply the radially-expansive force to the native valve annulus because no part of the prosthetic valve support that circumscribes the prosthetic valve is sandwiched between the prosthetic valve and the native valve annulus.

For some applications, prosthetic valve **150** is couplable to upstream support portion **60** at a plurality of positions along the length of the prosthetic valve. That is, a physician can couple the prosthetic valve at a plurality of depths within the support. For some applications, the prosthetic valve is couplable to the upstream support portion at a continuum of positions along the length of the prosthetic valve. That is, a physician can couple the prosthetic valve to the support at a continuum of depths within the support. For example, in some applications in which the prosthetic valve is configured to be coupled to the upstream support portion solely by the radially-expansive force, the prosthetic valve may be coupled to the upstream support portion at a continuum of positions along the length of the prosthetic valve.

For some applications, sealing between implant **180** and native valve **120** is facilitated by native leaflets **128** being pushed closed against the outer surface of the frame of the valve during systole, in a manner similar to that in which native valve leaflets of a healthy native valve coapt during systole.

For applications in which diameters d**4** and d**6** are relatively large, the proportion (e.g., the surface area) of the native leaflets that is pushed against the outer surface of the valve during systole is relatively large, thereby enhancing the sealing of the native leaflets with respect to the frame of the prosthetic valve. However, for some applications, beyond a given size, as diameters d**4** and d**6** increase, the native valve leaflets are pushed apart at the commissures, thereby potentially increasing a likelihood of paravalvular retrograde leakage of blood at the commissures. Therefore, for some applications of the present invention, prosthetic valve support **22** (and, typically, prosthetic valve **150**) are selected such that diameters d**4** and d**6** are less than 90% (e.g., **5** less than 80%, e.g., less than 60%, such as less than 50%) of diameter d**5** of the native valve (e.g., of the orifice of the native valve). Thus prosthetic valve support **22** facilitates sealing of the prosthetic valve with respect to the native valve, by facilitating closing of the native valve leaflets around the outer surface of the prosthetic valve.

In experiments conducted by the inventors, a prosthetic valve support **22** was implanted in two pigs. Both animals remained alive and stable (e.g., were hemodynamically stable, and had stable breathing rate and oxygen saturation) for a duration of sufficient length to withdraw delivery apparatus **140**, introduce a valve-delivery system, and deploy (e.g., implant) a prosthetic valve in opening **61** of the support. The period between implanting prosthetic valve support **22** and implanting the prosthetic valve was between 5 and 10 minutes. During this duration, the native valve of the animals functioned generally normally. For example, native leaflet movement and coaptation, and blood flow therebetween was generally normal during this duration.

It is thereby hypothesized that, following implantation of prosthetic valve support **22**, the heart of the subject is able to continue pumping blood sufficiently to support the subject (e.g., to maintain hemodynamic stability) for longer than a minute, e.g., longer than 2 minutes, e.g., longer than 5 minutes, such as longer than an hour. It is thereby hypothesized that a period of generally normal physiological activity of the subject of up to a minute, e.g., up to 2 minutes, e.g., up to 5 minutes, such as up to an hour, between implantation of prosthetic valve support **22** and implantation of a prosthetic valve (e.g., prosthetic valve **150**) is supported by prosthetic valve support **22**. It is thereby hypothesized that, for some applications, the implantation of implant **180** may be performed without the use of cardiopulmonary bypass. It is thereby further hypothesized that replacement of a native valve with implant **180**, may, for some applications, be performed in a human, "off-pump," as was performed in the pig experiments.

Reference is again made to FIG. **3**I. For some applications of the invention, the prosthetic valve that is expanded within, and coupled to, prosthetic valve support **22**, comprises a generally cylindrical prosthetic valve. For some applications, the prosthetic valve comprises a prior art prosthetic valve, e.g., a currently commercially-available prosthetic valve. That is, for some applications, prosthetic valve support **22** may be used to facilitate implantation of a prior art prosthetic valve, such as a currently commercially-available prosthetic valve. For some applications, and as shown in FIG. **3**I, the prosthetic valve comprises prosthetic valve **150**, which comprises (1) a generally cylindrical valve body **152** (e.g., a primary structural element), within which one or more prosthetic check valve elements (e.g., valve members, such as leaflets, a ball, or a disc) are disposed (not shown), and (2) one or more valve-anchoring elements **154** which protrude (e.g., radially) from the valve body. Typically, valve-anchoring elements **154** are disposed at a downstream end of prosthetic valve **150** (e.g., at a downstream end of valve body **152**), and protrude outward and upstream. For some applications, and as shown in FIG. **3**I, valve-anchoring elements **154** fold back toward valve body **152**, and are configured to sandwich stabilizing element **80**, clips **30** and/or native leaflets **128** between the valve-anchoring elements and the valve body. For some applications, prosthetic valve **150** does not comprise valve-anchoring elements **154**.

As described hereinabove, coupling of prosthetic valve **150** to prosthetic valve support **22** is typically facilitated by radially-expansive force applied by the valve to the support. Typically, prosthetic valve **150** comprises an expandable lattice-structure frame **151** (e.g., comprising a plurality of struts). For applications of the invention in which upstream support portion **60** comprises inwardly-protruding barbs **67** (e.g., as shown in FIGS. **1**A and **2**A), the barbs protrude into frame **151** (e.g., between struts thereof), thereby further facilitating coupling of the prosthetic valve to the prosthetic valve support.

Typically, at least portions of the inner surface of prosthetic valve **150** (e.g., of valve body **152**) are covered with a covering **156**, to facilitate channeling of blood through the valve body, as is known in the art. That is, at least portions of prosthetic valve **150** (e.g., of valve body **152**) are lined with covering **156**. Covering **156** may comprise the same material(s) as covering **64** described hereinabove, and/or may comprise other materials.

For some applications, an upstream portion of prosthetic valve **150** (e.g., of valve body **152**) alternatively or additionally comprises a netting **158**, which facilitates coupling of the prosthetic valve to prosthetic valve support **22**. Netting **158** may be disposed on the inner surface and/or the outer surface of the upstream portion of the prosthetic valve (e.g., of valve body **152**), and/or between the struts of frame **151**. Typically, netting **158** is disposed upstream of a point at which leaflets **182** contact (e.g., seal around) valve body **152**.

Typically, netting **158** facilitates coupling of prosthetic valve **150** to prosthetic valve support **22** by providing a higher-resolution lattice through which barbs **67** of the prosthetic valve support are configured to protrude. Netting **158** may additionally insulate respective metallic surfaces of the prosthetic valve and the prosthetic valve support (e.g., of frames **62** and **151**) from each other. It is hypothesized that this insulation reduces fatigue, corrosion, chipping and/or wear of the metallic surfaces, and/or electrostatic discharge between the metallic surfaces.

For some applications, a material that inhibits (e.g., prevents) tissue growth (e.g., polytetrafluoroethylene (PTFE), and/or pericardium) may be disposed on a surface of prosthetic valve **150** and/or prosthetic valve support **22** (e.g., clips **30** thereof). Alternatively or additionally, a material that facilitates (e.g., enhances) tissue growth (such as polyethylene terephthalate; PET) may be disposed on a surface of the prosthetic valve and/or the prosthetic valve support (e.g., clips **30** thereof), in order to facilitate sealing and/or coupling to the native valve.

It is hypothesized that the use of prosthetic valve support **22** advantageously facilitates delivery of a prosthetic valve via a catheter narrower than 28 Fr (i.e., less than 9.3 mm), e.g., narrower than 24 Fr (i.e., less than 8 mm), such as by allowing the use of a "minimalistic" prosthetic valve, comprising a generally cylindrical valve body, and valve members (e.g., leaflets) disposed therein, and comprising few or no other components and/or appendages. Typically, prosthetic valve support **22** is also delivered via a similarly narrow catheter, e.g., via the same catheter. The use of such a narrow catheter advantageously facilitates transluminal (e.g., transfemoral) delivery and implantation of the prosthetic valve and prosthetic valve support.

It is to be noted that, although FIGS. **3**A-I show prosthetic valve support **22** being implanted and used to facilitate implantation of a prosthetic valve, the techniques described may be applied to other prosthetic valve supports described herein (e.g., prosthetic valve supports **220**, **322**, **422** and **522**), mutatis mutandis.

Reference is made to FIGS. **4**A-F, which are schematic illustrations of a system **200** for facilitating controlled expansion and/or retrievability of upstream support portion **60**, in accordance with some applications of the invention. System **200** comprises one or more holding members **134**, reversibly coupled to upstream support portion **60** by one or more coupling leads **202** (e.g., coupling wires). Typically, two or more (e.g., three) holding members are coupled to the upstream support portion via two or more (e.g., three) coupling leads. Typically, the ends of each coupling lead **202** are disposed within holding members **134**, or more proximally (e.g., outside a body of the subject). Coupling leads **202** may comprise metallic wire, suture, or any other suitable material.

A portion (e.g., a middle portion) of each coupling lead **202** is disposed within (e.g., threaded and/or looped through) a respective portion of upstream support portion **60**, thereby coupling the upstream support portion to holding members **134**. Typically, this middle portion of each coupling lead is disposed through a peripheral region (e.g., close to an outer edge **69**) of the prosthetic valve support.

For example, and as shown in FIG. **4**A, three coupling leads **202** (e.g., coupling leads **202***a*, **202***b*, and **202***c*) couple three respective holding members **134** (e.g., holding members **134***a*, **134***b* and **134***c*) to upstream support portion **60**. One end of each coupling lead **202** extends from a respective holding member **134**, passes around (e.g., is looped and/or threaded through) upstream support portion **60**, and returns to the same holding member. Thereby, each coupling lead is configured to apply a respective annular pulling force to the entire upstream support portion, when the coupling lead is pulled.

For some applications of the invention, system **200** is configured to facilitate transluminal retrieval of upstream support portion **60** following expansion of the upstream support portion at the native valve. Upstream support portion **60** is deployed at the native valve, e.g., as described with reference to FIGS. 3C-F, mutatis mutandis. Should it be desirable and/or necessary to retrieve upstream support portion **60** into delivery tube **130**, and/or to remove the upstream support portion entirely from the subject, pulling of coupling leads **202** recompresses upstream support portion **60** into a generally cylindrical configuration, e.g., toward and/or into the compressed delivery configuration thereof (FIGS. **4**B-D). Subsequently, upstream support portion **60** may be withdrawn into delivery tube **130** (FIGS. **4**E-F).

System **200** may alternatively or additionally be configured to facilitate controlled expansion of upstream support portion **60**. During deployment of upstream support portion **60**, coupling leads **202** are gradually released (e.g., fed distally). This technique may be understood by considering FIGS. **4**B-F in reverse order, mutatis mutandis. Thereby, the rate of expansion of upstream support portion **60** is controllable. Alternative configurations and/or arrangements of coupling leads **202** may be used, e.g., to facilitate controlled expansion of different portions of upstream support portion **60**.

It is to be noted that the techniques described with reference to FIGS. **4**A-F may be used in combination with other upstream support portions described herein (e.g., upstream support portions **90** and **100**), mutatis mutandis.

Reference is made to FIG. **5**, which is a schematic illustration of a step in the implantation of prosthetic valve support **22**, in accordance with some applications (e.g., alternative applications) of the invention. For some applications, the step shown in FIG. **5** is performed after the implantation sequence steps shown in FIGS. **3**A-3D, and prior to the steps shown in FIGS. **3**F-**3**I, e.g., instead of or in addition to the step shown in FIG. **3**E, mutatis mutandis. FIG. **5** shows prosthetic valve support subsequent to the coupling of clips **30** to leaflets **128** of the native valve, and prior to the complete release (e.g., the complete expansion) of upstream support portion **60**.

For some applications of the invention, it may be desirable and/or necessary to hold clips **30** closer together than they would otherwise be disposed following complete release, and thereby expansion, of upstream support portion **60**. FIG. **5** shows clips **30** being held closer together, by holding of portions of upstream support portion **60** that are in the vicinity of clips **30**, closer together. At least one coupling lead (e.g., coupling wire) **210** is coupled to these portions of upstream support portion **60**, and holds the portions together, as shown in FIG. **5**. Coupling lead **210** may comprise metallic wire, suture, or any other suitable material.

At a later time (e.g., closer to a time at which prosthetic valve **150** is to be implanted, such as at the time at which the prosthetic valve is implanted), coupling lead **210** is released, such that the upstream support portion (and the prosthetic valve support as a whole) moves toward the configuration shown in FIGS. **3**F and/or **3**G.

For example, and as shown in FIG. **5**, two or more coupling leads **210** may extend through a holding member **212**, and loop through respective portions of upstream support portion **60**. The coupling leads are decoupled from the skirt by releasing one end of each coupling lead, and unlooping the coupling lead from the upstream support portion. For some applications, holding member **212** comprises holding member **134**, e.g., as described with reference to FIGS. **3**C-F.

It is to be noted that the techniques described with reference to FIG. **5** may be combined with other techniques and apparatus described herein. For example, the techniques described with reference to FIG. **5** may be used for implanting other prosthetic valve supports described herein, mutatis mutandis.

Reference is made to FIGS. **6**A-B, which are schematic illustrations of a prosthetic valve support **522**, comprising tissue-engaging elements **24** that are couplable to each other, and decouplable from each other (e.g., reversibly coupled to each other), in accordance with some applications of the invention. Prosthetic valve support **522** typically further comprises upstream support portion **60** and/or stabilizing element **80**, and the tissue-engaging elements of the prosthetic valve support typically comprise clips **30**. For some applications, prosthetic valve support **522** comprises prosthetic valve support **22** (e.g., as described with reference to FIGS. **1**A-D), and/or may be used in combination with techniques described herein (e.g., with reference to FIGS. **3**A-I and/or **8**), mutatis mutandis. For some applications, prosthetic valve support **522** does not comprise stabilizing element **80** (e.g., as described for prosthetic valve support **322** with reference to FIG. **2**C, mutatis mutandis), and/or does not comprise upstream support portion **60** (e.g., as described for prosthetic valve support **422** with reference to FIG. **2**D, mutatis mutandis). Similarly, the tissue-engaging elements of other prosthetic valve supports described herein may be reversibly coupled to each other as described for the tissue-engaging elements of prosthetic valve support **522**, mutatis mutandis. Typically, prosthetic valve support **522** is provided with tissue-engaging elements **24** fixedly coupled to each other, and configured to be transluminally, intracorporeally decoupled from each other. Alternatively or additionally, tissue-engaging elements **24** may be configured to be extracorporeally and/or intracorporeally (e.g., transluminally) couplable to each other by a physician.

FIGS. **6**A-B show prosthetic valve support **522** following implantation thereof at the native valve (e.g., as shown in FIGS. **3**A-F, mutatis mutandis), and before coupling of a prosthetic valve to the prosthetic valve support (e.g., as shown in FIGS. **3**H-I, mutatis mutandis), e.g., instead of or in addition to the step shown in FIG. **3**G, mutatis mutandis. For some applications, FIG. **6**A is thereby comparable to FIG. **3**G, mutatis mutandis.

FIG. **6**B shows a view from upstream of mitral valve **122** (e.g., from left atrium **124**), showing the valve (e.g., leaflets **128**) moving (e.g., beating) between open and closed states thereof. As is known in the art, each leaflet **128** of mitral valve **122** is generally defined as being divided into three scallops: scallops A**1**, A**2** and A**3** of the anterior leaflet, and scallops P**1**, P**2** and P**3** of the posterior leaflet. Tissue-engaging elements **24** are coupled to respective portions of leaflets **128** (e.g., scallops A**2** and P**2** of the anterior and posterior leaflets, respectively), and to each other, and thereby hold the portions of the leaflets to which they are coupled, close to each other (e.g., together). Portions of the leaflets that are not held close to each other (e.g., at least portions of scallops P**1**, P**3**, A**1** and A**3**) are typically generally able to move (e.g., flap) in response to beating of the heart. Thereby, the implantation of prosthetic valve support **522** shown in FIGS. **6**A-B generates two orifices **530**, each orifice defined by (e.g., surrounded by) a respective portion of each leaflet, and thereby, in effect, functioning as a respective check valve. For example, the native valve may function as two (e.g., parallel) check valves. For some applications of the invention, the resulting arrangement of leaflets **128** resembles the "double-orifice" arrangement of leaflets of a valve that has been repaired using the Alfieri stitch, as is known in the mitral valve repair art. Thereby, prosthetic valve support **522** is configured to be coupled to the native heart valve (e.g., to leaflets thereof) without eliminating check valve functionality of the native heart valve, by coupling together respective portions of the two leaflets, such that (1) the native leaflets define two orifices, and (2) the native valve functions as two (e.g., parallel) check valves (e.g., in a manner that is modified with respect to the natural function of the native valve).

Subsequently (e.g., immediately subsequently, or after more than a minute, e.g., after more than 2 minutes, e.g., after more than 5 minutes, such as after more than an hour), a prosthetic valve is transluminally delivered, and implanted at the native valve by coupling the prosthetic valve to prosthetic valve support **522** (e.g., as described with reference to FIGS. **3**H-I, mutatis mutandis). Prior to (e.g., immediately prior to) implantation of the prosthetic valve, tissue-engaging elements **24** are decoupled from each other, such that the tissue-engaging elements (and thereby leaflets **128**) are movable away from each other, and such that the prosthetic valve may be disposed therebetween during coupling of the prosthetic valve to the prosthetic valve support. For some applications of the invention, between (1) the decoupling of the tissue-engaging elements from each other, and (2) the coupling of the prosthetic valve to the prosthetic valve support, the prosthetic valve support allows (1) the native valve (e.g., the leaflets thereof) to define a single orifice, and (2) the native valve to function as a single check valve (e.g., as described with reference to FIG. **3**G, mutatis mutandis).

For some applications of the invention, tissue-engaging elements **24** are coupled to each other by a locking element (e.g., a locking wire), and the locking element is unlocked (e.g., the locking wire is cut or otherwise decoupled), prior to implantation of the prosthetic valve support. For some applications of the invention, tissue-engaging elements **24** are coupled to each other by a coupling lead that which is held in place, and removed, decoupled, and/or loosened immediately prior to implantation of the prosthetic valve. For example, the coupling lead may extend through a holding member and be looped through and/or around the tissue-engaging elements. For some such applications, the holding member may comprise holding member **212**, and the coupling lead may comprise coupling lead **210** (e.g., described with reference to FIG. **5**, mutatis mutandis), the coupling lead being coupled to tissue-engaging elements **24**, rather than to portions of the upstream support portion. For some applications of the invention, prosthetic valve support

522 is configured such that the tissue-engaging elements are decoupled (e.g., automatically) when the prosthetic valve is implanted at the native valve (e.g., when the prosthetic valve is expanded within the prosthetic valve support).

It is hypothesized that, following implantation of prosthetic valve support **522**, the heart of the subject is able to continue pumping blood sufficiently to support the subject and/or to maintain hemodynamic stability for longer than a minute, e.g., longer than 2 minutes, e.g., longer than 5 minutes, such as longer than an hour. It is thereby hypothesized that a period of generally normal physiological activity of the subject of up to a minute (e.g., up to 2 minutes, e.g., up to 5 minutes, such as up to an hour) between implantation of prosthetic valve support **522** and implantation of a prosthetic valve, is supported by prosthetic valve support **522**. It is thereby hypothesized that the implantation of an implant comprising prosthetic valve support **522** and a prosthetic valve, may be performed without the use of cardiopulmonary bypass. It is thereby hypothesized that replacement of a native valve with such an implant may be performed in a human, "off-pump."

It is to be noted that the techniques described with reference to FIGS. **6**A-B may be combined with other techniques and apparatus described herein. For example, tissue-engaging elements (e.g., clips) of other prosthetic valve supports described herein may be reversibly coupled to each other, so as to achieve the double-orifice configuration of the native valve described with reference to FIGS. **6**A-B, mutatis mutandis.

Reference is made to FIG. **7**, which is a schematic illustration of a prosthetic valve support **220**, comprising upstream support portion **60** and three clips **30** (or other tissue-engaging elements **24**), in accordance with some applications of the invention. Clips **30** are typically coupled to upstream support portion **60** via connectors **70**, as described hereinabove, mutatis mutandis. For some applications, and as shown in FIG. **7**, prosthetic valve support **220** is configured to be coupled to mitral valve **122** of the subject. One clip **30** is configured to be coupled to anterior leaflet **128***a* of the mitral valve (e.g., to the A**2** scallop thereof), and two clips are configured to be coupled to posterior leaflet **128***b* (e.g., to the P**1** and P**3** scallops thereof, respectively). For some applications, prosthetic valve support **220** is configured to be coupled to a native tricuspid valve of the subject, and each clip **30** is configured to be coupled to a respective leaflet of the tricuspid valve.

It is to be noted that the techniques described with reference to FIG. **7** may be combined with other techniques and apparatus described herein. For example, other prosthetic valve supports described herein (e.g., prosthetic valve supports **220**, **322**, **422** and **522**) may comprise three tissue-engaging elements, mutatis mutandis.

Reference is made to FIG. **8**, which is a schematic illustration of implantation, in heart **250** of the subject, of a prosthetic valve **240**, facilitated by prosthetic valve support **22**, in accordance with some applications of the invention. For some applications, prosthetic valve **240** comprises and/or has features of prosthetic valve **150**, described hereinabove. For some applications, and as shown in FIG. **3**H, both the prosthetic valve support and the prosthetic valve are configured to be delivered from the upstream side of mitral valve **122**, e.g., transfemorally and/or transseptally. For some applications of the invention, the prosthetic valve is configured to be delivered via a retrograde approach. For example, and as shown in FIG. **8**, following implantation of prosthetic valve support **22** at mitral valve **122**, prosthetic valve **240** is delivered via left ventricle **126**, e.g., via aorta **252** such as via the femoral artery of the subject. Alternatively, prosthetic valve **240** may be delivered transapically. For applications in which the prosthetic valve is delivered via a retrograde approach, prosthetic valve support **22** is typically delivered as described hereinabove, but may alternatively be delivered via a retrograde approach.

It is to be noted that the techniques described with reference to FIG. **8** may be combined with other techniques and apparatus described herein. For example, the techniques described with reference to FIG. **8** may be used for implanting other prosthetic valves described herein, and/or for delivering a prosthetic valve to other prosthetic valve supports described herein, mutatis mutandis.

Reference is made to FIGS. **9**A-C, which are schematic illustrations of prosthetic valve supports, each comprising upstream support portion **60**, coupled to tissue-engaging elements **24** (comprising clips **30**) via one or more variable-length connectors **260**, in accordance with respective applications of the invention. Variable-length connectors **260** are typically positioned in the same or similar way as connectors **70**, and typically perform the same or similar functions as connectors **70**, described hereinabove.

FIG. **9**A shows a prosthetic valve support **270**, comprising variable-length connectors **260**, embodied as adjustable-length connectors **272**, in accordance with some applications of the invention. Connectors **272** comprise a holding wire **274**, which is slidably coupled to upstream support portion **60**, is fixedly coupled to tissue-engaging elements **24**, and defines a rack **276**, comprising a plurality of teeth **277**, disposed along at least part of the length of the holding wire. The distance between upstream support portion **60** (e.g., inner perimeter **68** thereof) and each tissue-engaging element **24** is adjustable by adjusting the length of the respective holding wire **274** that is disposed between the upstream support portion and the tissue-engaging element. Typically, this length is adjusted by pulling the holding wire proximally. Thereby, the length of connectors **272** is variable, by the connectors being adjustable.

An engaging element **278** (e.g., a pawl, a ridge, or a tooth), typically within a ratchet housing **280**, allows the length of holding wire **274** between the upstream support portion and the clip to be shortened, but not to be lengthened. Thereby, holding wire **274** (e.g., rack **276** thereof) and ratchet housing **280** (e.g., engaging element **278** thereof) act as a ratchet. For some applications, and as shown in FIG. **9**A, ratchet housing **280** is movable with respect to upstream support portion **60**, and is slid distally over holding wire **274**, such as by a pusher **282** (e.g., a controller tube). Alternatively, ratchet housing **280** is fixedly coupled to upstream support portion **60**, e.g., such that the length of holding wire **274** is adjusted by pulling the holding wire proximally. Typically, but not necessarily, the length of holding wire **274** (and thereby of connectors **272**) is adjusted subsequent to coupling of clips **30** to the native leaflets, and further typically, also subsequent to deployment of upstream support portion **60**.

FIG. **9**B shows a prosthetic valve support **290**, comprising variable-length connectors **260**, embodied as elastic connectors **292** (e.g., stretchable connectors), in accordance with some applications of the invention. Connectors **292** comprise one or more (e.g., two) elastic elements **294**, such as tension springs (e.g., coil tension springs). The distance between upstream support portion **60** (e.g., inner perimeter **68** thereof) and each clip is variable due to stretching and contracting of elastic elements **294**. Thereby, the length of connectors **292** is variable, by the connectors being elastic.

The length, elasticity and/or force constant of elastic elements **294** may be adapted to the native valve to which prosthetic valve support **290** is coupled, and/or to the individual subject (e.g., pre-selected according to the native valve and/or the individual subject). For example, elastic elements that have a relatively low force constant may allow leaflets of the native valve to move more freely, and elastic elements that have a relatively high force constant may couple the prosthetic valve support to the native valve more fixedly. Alternatively or additionally, connectors **260** may be configured to stretch and contract with movement (e.g., flapping) of the leaflets of the native valve, may thereby allow the leaflets to move more freely compared to some inelastic connectors, and may thereby facilitate the coupling of the prosthetic valve support to the native valve without eliminating check valve functionality of the native valve.

FIG. **9**C shows a prosthetic valve support **300**, comprising variable-length connectors **260**, embodied as elastic connectors **302**, in accordance with some applications of the invention. Connectors **302** comprise an elastic element **304**, such as a tension spring (e.g., a coil tension spring). For some applications, elastic element **304** comprises elastic element **294**, described with reference to FIG. **9**B. Connectors **302** further comprise a restrictor **306**, which restricts elasticity of element **304**. Typically, restrictor **306** holds elastic element **304** in an expanded (e.g., stretched) state. Typically, restrictor **306** is releasable (e.g., decouplable) from elastic element **304**, so as to allow the elastic element to contract.

For some applications, restrictor **306** may be mechanically releasable (e.g., removable) by the user. For some applications, and as shown in FIG. **9**C, restrictor **306** may comprise a material that disintegrates in the body (e.g., a material that is at least in part soluble and/or biodegradable and/or biosorbent). For such applications, restrictor **306** typically disintegrates over a predictable period of time e.g., between 15 minutes and 1 week, such as between 30 minutes and 3 days, for example, between 1 hour and 1 day. For some applications, restrictor **306** is configured to decouple from (i.e., release) elastic element **304** gradually, e.g., in stages. For some applications, restrictor **306** is coupled to elastic element **304** and/or another part of prosthetic valve support **300**, such that, following the release of the elastic element, the restrictor is retained, so as not to enter the vasculature of the subject.

For some applications of the invention, prosthetic valve support **300** and connectors **302** are used in instances in which it is desirable to have a first period during which the connectors are longer (e.g., prior to implantation of a prosthetic valve), and a second period during which the connectors are shorter (e.g., subsequent to implantation of the prosthetic valve).

Reference is again made to FIGS. **9**A-C. It should be noted that throughout this patent application, including in the claims, the term "variable", with respect to the length of the connectors that couple tissue-engaging elements **24** (e.g., clips **30**) to upstream support portion **60**, includes (1) length variability due to intervention, such as a physician adjusting the length (e.g., as described for adjustable-length connectors **272**), and (2) length variability due to elasticity and/or another configuration that facilitates the connector changing length, such as without intervention (e.g., as described for elastic connectors **292** and **302**). It is hypothesized that, for some applications, connector length variability (1) facilitates reduction of valve regurgitation prior to implantation of the prosthetic valve (2) provides adjustability for anatomical differences (e.g., leaflet size) between subjects, and/or (3) increases stability of the prosthetic valve, e.g., by reducing axial rotation of the prosthetic valve, such as by the connector length being shortened after implantation of the prosthetic valve.

It is to be noted that the apparatus and techniques described with reference to FIGS. **9**A-C may be combined with other techniques and apparatus described herein. For example, any of the prosthetic valve supports may comprise variable-length connectors **260** (e.g., adjustable-length connectors **272**, elastic connectors **292**, and/or elastic connectors **302**), mutatis mutandis. Similarly, connector length adjustment may be used in combination with the implantation techniques described with reference to FIGS. **3**A-I and/or **8**, mutatis mutandis.

Reference is again made to FIGS. **1**A-**9**C. For some applications of the invention, one or more of the elements, portions and/or components described hereinabove comprise radiopaque markers so as to facilitate implantation thereof (e.g., by using imaging techniques such as fluoroscopy). For example, tissue-engaging elements **24** (e.g., clips **30**) and/or stabilizing element **80** may comprise radiopaque markers, e.g., so as to facilitate positioning (e.g., orientation) of the prosthetic valve support with respect to the native valve. Alternatively or additionally, inner perimeter **68** of upstream support portion **60** and/or stabilizing element **80** may comprise radiopaque markers, e.g., so as to indicate the opening(s) in which the prosthetic valve is to be implanted. Alternatively or additionally, the prosthetic valve may comprise radiopaque markers to facilitate positioning thereof with respect to the prosthetic valve support.

Reference is again made to FIGS. **1**A-**9**C. For some applications of the invention, the tissue-engaging elements of the prosthetic valve supports described hereinabove are movable with respect to each other at at least some time subsequent to the coupling of the tissue-engaging elements being coupled to the leaflets of the native valve. For example, tissue-engaging elements **24** (e.g., clips **30**) of prosthetic valve support **22** are movable with respect to each other, e.g., as shown in FIG. **3**G. Similarly, tissue-engaging elements **24** (e.g., clips **30**) of prosthetic valve support **522** are movable with respect to each other once they have been decoupled from each other.

Reference is again made to FIGS. **1**A-**9**C. The prosthetic valve supports described hereinabove are typically configured to be coupled to the leaflets of the native valve without eliminating check-valve functionality of the native valve. That is, although the coupling of the prosthetic valve support to the native valve may alter the position and/or movement of the native leaflets, the native valve still facilitates at least some net one-way movement of blood therethrough (e.g., as described with reference to FIGS. **3**G and **6**A-B). For some such instances, the altered position and/or movement of the native leaflets may, in fact, enhance check valve functionality of the native valve, thereby substantially "repairing" the native valve. For some such instances, a physician may choose not to implant a prosthetic valve during the same procedure as the implantation of the prosthetic valve support, but instead may choose to allow the subject to return to activities of daily living, whilst retaining the option to implant a prosthetic valve at a later date. That is, for some applications of the invention, the prosthetic valve support is configured to be implanted without a prosthetic valve, and to provide (1) repair of the native valve, and (2) an implantation site that is pre-prepared for subsequent implantation of a prosthetic valve at a later date, should such implantation be subsequently considered necessary.

It is to be noted that, although some techniques described hereinabove are generally illustrated as being used at the mitral valve of the subject, the scope of the invention includes implanting a prosthetic valve support and prosthetic valve (e.g., those described hereinabove) at other native heart valves of the subject, such as at the tricuspid valve, the aortic valve, or the pulmonary valve of the subject, mutatis mutandis.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

The invention claimed is:

**1**. A heart valve repair system, comprising:
- a delivery sheath having a proximal end and a distal end; and
- an implant configured to be coupled to first and second native leaflets of a native heart valve of a patient, the implant comprising:
  - a frame (1) comprising a braided structure of intertwining strands and (2) having a surface configured to contact an upstream surface of the native heart valve; and
  - first and second gripping members coupled to the frame, each of the first and second gripping members including (i) a ventricular arm, the ventricular arm having first and second ends, and (ii) an atrial arm, wherein for each of the gripping members:
    - (A) the ventricular arm is movable toward a central longitudinal axis of the implant, and
    - (B) due to the moving of the ventricular arm toward the central longitudinal axis, the second end of the ventricular arm moves toward the central longitudinal axis more than the first end of the ventricular arm moves toward the central longitudinal axis of the implant,

wherein the implant is disposed in the delivery sheath in a delivery state in which:
- the frame has a proximal end, closer to the proximal end of the delivery sheath, and a distal end, closer to the distal end of the delivery sheath,
- the frame is shaped to define a wall fully surrounding, from a proximal end of the wall to a distal end of the wall, the central longitudinal axis of the implant, the proximal end of the wall defining a proximal opening of the frame, and the distal end of the wall defining a distal opening of the frame, and
- the distal end of the wall is disposed proximally to the second end of the ventricular arm of each of the gripping members.

**2**. The heart valve repair system of claim **1**, wherein the frame comprises a lattice structure frame.

**3**. The heart valve repair system of claim **1**, wherein the frame comprises a plurality of struts.

**4**. The heart valve repair system of claim **1**, wherein:
- the implant is disposed in the delivery sheath in an extended state, and
- the implant is configured to assume an implanted state in which, following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, a longitudinal length of the implant in the implanted state is shorter than a longitudinal length of the implant while in the extended state.

**5**. The heart valve repair system of claim **1**, wherein the implant is configured to assume an implanted state following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, and wherein, in the implanted state, the first and second gripping members are configured to allow the first and second native leaflets to function as a check-valve.

**6**. The heart valve repair system according to claim **1**, wherein the implant does not comprise a prosthetic heart valve.

**7**. The heart valve repair system of claim **1**, wherein for each of the gripping members, one of the arms of the gripping member has a free end, and wherein the implant is disposed within the delivery sheath in a manner in which a flexible portion of the implant is disposed proximal to the free ends of the gripping members.

**8**. The heart valve repair system of claim **7**, wherein the flexible portion comprises nitinol and fabric.

**9**. A heart valve repair system, comprising:
- a delivery sheath having a proximal end and a distal end; and
- an implant configured to be coupled to first and second native leaflets of a native heart valve of a patient, the implant comprising:
  - a frame having a surface configured to contact an upstream surface of the native heart valve; and
  - first and second gripping members coupled to the frame, each of the first and second gripping members including (i) a ventricular arm, the ventricular arm having first and second ends, and (ii) an atrial arm, wherein for each of the gripping members:
    - (A) the ventricular arm is movable toward a central longitudinal axis of the implant, and
    - (B) due to the moving of the ventricular arm toward the central longitudinal axis, the second end of the ventricular arm moves toward the central longitudinal axis more than the first end of the ventricular arm moves toward the central longitudinal axis of the implant,

wherein the implant is disposed in the delivery sheath in a delivery state in which:
- the frame has a proximal end, closer to the proximal end of the delivery sheath, and a distal end, closer to the distal end of the delivery sheath,
- the frame is shaped to define a wall fully surrounding, from a proximal end of the wall to a distal end of the wall, the central longitudinal axis of the implant, the proximal end of the wall defining a proximal opening of the frame, and the distal end of the wall defining a distal opening of the frame, and
- the distal end of the wall is disposed proximally to the second end of the ventricular arm of each of the gripping members, and

wherein the implant is configured to assume an implanted state in which, following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, the first and second gripping members form the first and second native leaflets into a double orifice, each orifice configured to function as a respective check-valve.

**10**. The heart valve repair system of claim **9**, wherein:
- the implant is disposed in the delivery sheath in an extended state, and

the implant is configured to assume an implanted state in which, following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, a longitudinal length of the implant in the implanted state is shorter than a longitudinal length of the implant while in the extended state.

**11**. The heart valve repair system of claim **9**, wherein the implant is configured to assume an implanted state following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, and wherein, in the implanted state, the first and second gripping members are configured to allow the first and second native leaflets to function as a check-valve.

**12**. The heart valve repair system according to claim **9**, wherein the implant does not comprise a prosthetic heart valve.

**13**. The heart valve repair system of claim **9**, wherein for each of the gripping members, one of the arms of the gripping member has a free end, and wherein the implant is disposed within the delivery sheath in a manner in which a flexible portion of the implant is disposed proximal to the free ends of the gripping members.

**14**. The heart valve repair system of claim **13**, wherein the flexible portion comprises nitinol and fabric.

**15**. A heart valve repair system, comprising:

a delivery sheath having a proximal end and a distal end; and

an implant configured to be coupled to first and second native leaflets of a native heart valve of a patient, the implant comprising:

a frame having a surface configured to contact an upstream surface of the native heart valve; and

first and second gripping members coupled to the frame, each of the first and second gripping members including (i) a ventricular arm, the ventricular arm having first and second ends, and (ii) an atrial arm, wherein for each of the gripping members:

(A) the ventricular arm is movable toward a central longitudinal axis of the implant, and

(B) due to the moving of the ventricular arm toward the central longitudinal axis, the second end of the ventricular arm moves toward the central longitudinal axis more than the first end of the ventricular arm moves toward the central longitudinal axis of the implant,

wherein the implant is disposed in the delivery sheath in a delivery state in which:

the frame has a proximal end, closer to the proximal end of the delivery sheath, and a distal end, closer to the distal end of the delivery sheath,

the frame is shaped to define a wall fully surrounding, from a proximal end of the wall to a distal end of the wall, the central longitudinal axis of the implant, the proximal end of the wall defining a proximal opening of the frame, and the distal end of the wall defining a distal opening of the frame, and

the distal end of the wall is disposed proximally to the second end of the ventricular arm of each of the gripping members, and

wherein the heart valve repair system further comprises an elongate control member that is:

movable within the delivery sheath,

reversibly couplable to the implant, and

extracorporeally controllable to facilitate the moving of each of the ventricular arms,

wherein in the delivery state, the wall of the frame surrounds a space through which the elongate control member is movable.

**16**. The heart valve repair system of claim **15**, wherein the elongate control member is decouplable from the implant and withdrawable through the frame following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant.

**17**. The heart valve repair system of claim **15**, wherein:

the implant is disposed in the delivery sheath in an extended state, and

the implant is configured to assume an implanted state in which, following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, a longitudinal length of the implant in the implanted state is shorter than a longitudinal length of the implant while in the extended state.

**18**. The heart valve repair system of claim **15**, wherein the implant is configured to assume an implanted state following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, and wherein, in the implanted state, the first and second gripping members are configured to allow the first and second native leaflets to function as a check-valve.

**19**. The heart valve repair system according to claim **15**, wherein the implant does not comprise a prosthetic heart valve.

**20**. The heart valve repair system of claim **15**, wherein for each of the gripping members, one of the arms of the gripping member has a free end, and wherein the implant is disposed within the delivery sheath in a manner in which a flexible portion of the implant is disposed proximal to the free ends of the gripping members.

**21**. The heart valve repair system of claim **20**, wherein the flexible portion comprises nitinol and fabric.

**22**. A heart valve repair system, comprising:

a delivery sheath having a proximal end and a distal end; and

an implant configured to be coupled to first and second native leaflets of a native heart valve of a patient, the implant comprising:

a frame having a surface configured to contact an upstream surface of the native heart valve; and

first and second gripping members coupled to the frame, each of the first and second gripping members including (i) a ventricular arm, the ventricular arm having first and second ends, and (ii) an atrial arm, wherein for each of the gripping members:

(A) the ventricular arm is movable toward a central longitudinal axis of the implant, and

(B) due to the moving of the ventricular arm toward the central longitudinal axis, the second end of the ventricular arm moves toward the central longitudinal axis more than the first end of the ventricular arm moves toward the central longitudinal axis of the implant,

wherein the implant is disposed in the delivery sheath in a delivery state in which:

the frame has a proximal end, closer to the proximal end of the delivery sheath, and a distal end, closer to the distal end of the delivery sheath,

the frame is shaped to define a wall fully surrounding, from a proximal end of the wall to a distal end of the wall, the central longitudinal axis of the implant, the proximal end of the wall defining a proximal opening of the frame, and the distal end of the wall defining a distal opening of the frame, and

the distal end of the wall is disposed proximally to the second end of the ventricular arm of each of the gripping members, and

wherein the implant further comprises first and second gripping member mounts to which the first and second gripping members are mounted, respectively.

**23**. The heart valve repair system according to claim **22**, wherein each of the gripping member mounts is shaped as a strip.

**24**. The heart valve repair system of claim **22**, wherein:

the implant is disposed in the delivery sheath in an extended state, and

the implant is configured to assume an implanted state in which, following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, a longitudinal length of the implant in the implanted state is shorter than a longitudinal length of the implant while in the extended state.

**25**. The heart valve repair system of claim **22**, wherein the implant is configured to assume an implanted state following the moving of the ventricular arm of each of the gripping members toward the central longitudinal axis of the implant, and wherein, in the implanted state, the first and second gripping members are configured to allow the first and second native leaflets to function as a check-valve.

**26**. The heart valve repair system according to claim **22**, wherein the implant does not comprise a prosthetic heart valve.

**27**. The heart valve repair system of claim **22**, wherein for each of the gripping members, one of the arms of the gripping member has a free end, and wherein the implant is disposed within the delivery sheath in a manner in which a flexible portion of the implant is disposed proximal to the free ends of the gripping members.

**28**. The heart valve repair system of claim **27**, wherein the flexible portion comprises nitinol and fabric.

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